

Job Title:	Director of Operations, Imperial Clinical Trials Unit
Department/Division/Faculty:	Imperial Clinical Trials Unit (ICTU)/ SPH/ Medicine
Campus location:	White City (remote working until further notice)
Job Family/Level:	Professional Services, Level 5
Responsible to:	ICTU Director and Deputy Director
Line Management responsibility for:	Operations Managers, Business Development Manager, Quality Assurance Manager, and ICTU PPI Coordinator
Key Working Relationships (internal):	Working closely with the Unit Director and Deputy Director, Head of Statistics, Head of Commercial Portfolio, Head of Clinical Data Systems, Business Development team, staff within ICTU, Departmental Manager and Administrative team, QA Manager and QA team, ICTU Therapeutic Area Leads, Lead Investigators across Imperial College, Divisional / Departmental /Faculty Management Teams, Head of Research Operations (Joint Research Office), Head of Regulatory Compliance (Joint Research and Compliance Office).
Key Working Relationships (external):	Clinical Investigators / collaborators within Imperial College Healthcare NHS Trust and further afield, the UKCRC Registered CTU Network, Funders e.g. charity, government and commercial entities, Sponsor organisations, other research institutions and organisations, local and national research networks e.g. UKCRN, ethical and regulatory bodies (e.g. HRA, MHRA).
Contract type:	Full-time and fixed term for three years in the first instance with the possibility to extend (subject to funding renewal)

Background to the Post:

ICTU is a UKCRC registered clinical trials unit that brings together academic, clinical and trial management expertise from across the Imperial College Academic Health Science Centre (IC AHSC) to deliver world class clinical trials of all phases and designs. The Unit also collaborates with members of the designated Academic Health Science Network for North West London, Imperial College Health Partners, other national clinical and scientific key opinion leaders, other CTUs and with Industry.

The Unit leads primarily on the design, conduct and analysis of national and international multi-centre trials and staff, with specialist disease and methodological knowledge, have input at all stages of the trial lifecycle; thus ensuring all activities are conducted according to the principles of ICH GCP and in compliance with the appropriate regulatory and ethical requirements. The Unit also manages a small early phase portfolio with an emphasis on the design and analysis aspects of these studies. Current therapeutic areas of expertise include Oncology, Cardiovascular and Diabetes, Emergency Medicine and Critical Care, Infectious Diseases, Surgery, Robotics and Respiratory, but 25% of the portfolio arises from other therapeutic areas.

Purpose of the Post:

The Director of Operations is responsible for providing high level oversight of operational activities including trial management, data management and quality assurance. They will undertake continuous review and assessment of operations against organisational objectives, in order to maintain and maximise the quality, efficiency, effectiveness and compliance of trial procedures within financial limits.

This post also has a key leadership and strategic role alongside the other senior staff in the management and development of ICTU. The senior team works closely with the Unit Director and Deputy Director and other multi-professional groups both inside and outside Imperial College.

The Director of Operations provides senior business and research management expertise and input to drive ICTU strategic development and delivery. The role requires an extensive understanding of, and senior level expertise in, research management and governance and provision of infrastructure support.

Under the overall direction of the Unit Director, the post holder will be responsible, alongside the other senior staff, for ensuring strong and effective working links between ICTU and all associated organisations and bodies within the college. They will act as the key link with other Trials Units, Sponsor organisations, potential Sponsor organisations, the UKCRN, and other relevant external organisations and groups working with others as required

The post holder will be essential in ensuring the effective development, conduct, management and delivery of the ICTU portfolio trials, and other high-quality research, that come through the unit. They will also forge closer links with other research groups within Imperial and expand the research collaborative network.

Key Responsibilities

Strategy

- Work closely with the senior management team to support the Unit Director and Deputy Director in the development, implementation and annual review of ICTU's Business Plan and strategy.
- Identify and develop the infrastructure and systems necessary for the smooth and efficient operational running of ICTU and as needed for the implementation of ICTU strategy, working with and seeking input and advice from the Sectional teams, other Imperial departments and stakeholders as appropriate.
- Attend and / or Chair, and contribute to, key committees and management groups including the ICTU Senior Management team, ICTU Scientific Board and ICTU Forum, as well other Sectional meetings and College wide Committees
- Ensure Public Patient Involvement activities across all therapeutic areas within the unit are maintained.
- Ensure continuity of staff and resources.

Clinical Trials

- Work with the other senior staff to support the Unit Director and Deputy Director to establish a range of clinical trials in ICTU's portfolio.
- In collaboration with the Joint Research Office and other senior operational staff, oversee the negotiation of the contracts for new trials to ensure the conditions are achievable and desirable and that reimbursement is adequate to achieve a high standard of work.
- Oversee the management and delivery of the trials run by ICTU, supporting the Operation Managers, Trial Managers, Clinical Data Systems and Statistical staff to ensure the trials are run in an efficient way, conforming to their study protocols, SOP's, Manuals of Operations and all applicable regulatory and ethical standards.
- Provide operational support and advice to the other Sections in the Unit including Statistics, Business Development, Clinical Data Systems, Quality Assurance and Commercial to ensure activities are conducted in compliance with relevant standards and within the necessary legal framework.

Trials Unit Infrastructure and Management

- Maintain senior management oversight of ICTU's operational research infrastructure and management activities. This includes mapping current and monitoring future activity and funding and working with the senior management team to ensure appropriate organisation of resources across ICTU.
- Participate in ICTU financial planning taking a lead on the operational side and ensuring, along with the senior management team, that the unit remains financially sound and capable of growth and achieving its full potential.
- Participate in planning and delivery of training taking a lead on the operational side and ensuring, along with the senior management team that the unit remains staffed by appropriately trained personnel.
- Lead on and co-ordinate grant applications for funding for the unit

Staff / Team Management

- To provide professional leadership to all operational staff at all levels throughout the Unit
- Oversee and/or assist in the recruitment and on-going management (where appropriate), development and support of ICTU multi-professional staff team including: Operation Managers, Business Development Manager, PPI Co-ordinator and Quality Assurance Manager.
- Maintain an awareness of best practice with regard to managing and developing staff using appropriate team building and change management skills to ensure the cohesiveness, effectiveness and continuity of the unit.
- Ensure that appropriate facilities and management services are provided for ICTU staff working both within the Trials Unit and externally around the country and overseas.
- Contribute to the development of local and national training programmes as required.

Finance and General Management

- Contribute to the management, monitoring, control, and reporting of budgets, working closely with the Unit Director and Deputy Director, Departmental Manager, ICTU Administrators, Joint Research Office, School and Divisional Administration and appropriate external organisations.
- Advise on financial and contractual management for projects and awards in conjunction with the Departmental Manager, senior Operational Managers, Administrative Assistant/Project Administrator and Head of Commercial Portfolio.

Information Performance

- Oversee the production of key ICTU documents, plans and reports as required and in conjunction with the Unit Departmental Manager. These may include the production of presentations, including metrics, financial plans and annual reports.
- Ensure that information is disseminated across the network as appropriate, ensure that information is uploaded as required onto local and national databases in a timely and accurate way, and generally ensure that all ICTU information is managed to the highest operational and regulatory standards. Liaising with Faculty Administration on issues of Data Protection where appropriate.
- Liaise with the Head of Clinical Data Systems to ensure the maintenance of effective information systems and staff.

Quality Assurance

- Oversee the activities of the Quality Assurance team who are responsible for the implementation of the Quality Management System (QMS) across the trial portfolio.
- Contribute to the planning and conduct of trial and systems audit activity
- Provide support, and lead where necessary, on the escalation of trial related issues to Faculty level.
- Assist with the preparation and conduct for any GCP inspection or 3rd party audit within ICTU
- Contribute to QA team - Imperial JRCO Oversight meetings
- Contribute to the review of ICTU systems and processes to ensure continued compliance with relevant legislation.

Communication and Relationships

- Working with the senior staff to develop and deliver an effective communication and information management plan, following best practice, within and external to ICTU. This may include the preparation and delivery of presentations, reports and newsletters to ICTU staff, trial Sponsors, potential sponsors, the Investigators and staff of the trials run by ICTU and other relevant organisations and stakeholders.
- Support the Unit Director and Deputy Director in representing the unit at a local and national level, deputising for them as appropriate.

- Establish and maintain effective working relationships with all relevant organisations and individuals, including ICTU members, other CTU's, other providers of NHS services, staff from the Research Networks, staff from the rest of ICTU and other Schools/Institutes and Departments (SID's) and departments of Imperial – especially the Joint Research Office, Joint Research and Compliance Office, Human Resources and Research Services, Principal/Chief Investigators and other research site staff and other relevant staff and outside organisations (especially Sponsors and potential sponsors) and suppliers.
- Represent ICTU's interests on National Bodies such as the Meetings of Registered Trials Units Directors, and UKCRN Working Groups i.e. Trial Management and the Training and Development groups.
- Liaise on a regular basis with:
 - All ICTU staff
 - SPH Divisional Administration
 - Senior JRO and JRCO staff
 - Research Services staff
 - Human Resources staff
 - Chief/Principal Investigators and other Key Opinion Leader's
 - Sponsor and potential sponsor organisations
 - Outside contractors
 - UKCRN Co-ordinating Centre staff
 - Local Research Networks staff and organisations
 - Other Trials Unit staff
 - Other research groups within Imperial
- Provide input on behalf of ICTU on operational practice and procedures for national and international surveys

Person Specification

Requirements	Essential (E)/ Desirable (D)
Candidates/post holders will be expected to demonstrate the following:	
Education, Experience and Knowledge	
Professional knowledge of clinical research management acquired through a degree or equivalent, and supplemented by (a) specialist training to doctorate or equivalent (for example in health science, clinical trials, nursing, biosciences, quantitative science subject), and (b) management qualification (for example in management, PRINCE2), or (c) equivalent experience	E
Proven ability of high-quality professional leadership, both strategic and operational, including experience of leadership in organisational change	E
Experience of clinical research and operations management at a senior level, to include extensive practical experience in the planning, coordination and conduct of clinical research trials and studies including RCTs	E
Demonstrated effective line management of research and research-related staff, and leadership and management of teams and Sections	E
Experience of successful financial management	E
Significant experience of working in the NHS and/or academia	E
Understanding of research policies relating to clinical research	E
Understanding of FEC costing	E
Experience of effective project management	E
Knowledge of the research governance, regulatory and legislative framework for conducting clinical research trials and studies, including Good Clinical Practice	E
Knowledge of current national systems and structures for the funding and support of clinical research in the NHS	E
Skills & Abilities	
Proven organisational and leadership skills, including ability to provide leadership in the management of change	E
Ability to communicate highly complex, sensitive or contentious information both orally and in writing, internally to colleagues and externally to a range of audiences, including large groups	E
Ability to prepare and deliver presentations and performance / operation metrics and reports to a high standard	E
Proven excellent interpersonal and negotiating skills to work with clinical, scientific and administration / management colleagues at all levels across a range of organisations	E
Ability to analyse and interpret highly complex information, and ability to make judgements regarding a range of highly complex research management issues	E
Strong problem-solving skills	E
Excellent decision-making skills	E
Ability to plan, manage, adjust and deliver complex projects, involving multiple agencies and individuals and a broad range of activities to tight deadlines	E
Ability to work with minimal day-to-day supervision	E
Good IT skills, particularly in the use of Web applications and MS Office applications	E
Flexible approach to working and a desire to develop knowledge	E
Attention to detail	E
Highly motivated, with the ability to influence and inspire others.	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) Encourage inclusive participation and eliminate discrimination
- 3) Communicate regularly and effectively within and across teams
- 4) Consider the thoughts and expectations of others
- 5) Deliver positive outcomes
- 6) Develop and grow skills and expertise
- 7) Work in a planned and managed way

Employees are 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.

Committed to equality and valuing diversity, we are an Athena SWAN Silver Award winner, a Stonewall Diversity Champion, a Disability Confident Leader and work in partnership with GIRES to promote respect for trans people.

[01 March 2021]