Job Description

Job Title:	Head of Registry Operations
Reporting to:	Associate Director, Data and Quality Improvement (QI)
Responsible for:	Registry Clinical Data Manager, Registry Development Manager, Registry Software Analyst, Registry Coordinator
Directorate:	Research and Healthcare Data
Hours of work:	Full Time 35 Hours per week
Salary:	£64,000 plus £3,000 London Weighting or £450 Home Working Allowance
Contract:	Permanent
Location:	London Office based or Home based*.

*Some travel across the UK will be required, with occasional international travel.
If London based, the postholder will be required to attend the office a minimum of two days per week.

Background

The UK CF Registry has been sponsored and hosted by Cystic Fibrosis Trust since 2007. It is an internationally recognised database of over 11,000 consenting people with CF in the UK (~99% of the UK CF population).

The Registry collects longitudinal demographic, treatment, and health outcomes data (collected as part of routine clinical care) to improve the health of people with cystic fibrosis. This data is used to drive research into new treatments and improve outcomes, monitor the safety and effectiveness of medications, to provide evidence to support improvements in clinical care as well as supporting clinical trials through pragmatic data collection – all toward helping deliver a life unlimited for everyone affected by CF across the UK.

The Registry is entering a period of strategic evolution to enhance its capabilities, infrastructure, and impact. The Head of Registry Operations will play a critical role in maintaining operational excellence and stakeholder confidence during this transformation, working closely with colleagues leading strategic implementation.

Main Job Role

To provide leadership and management for the UK CF Registry team, building upon the success of the Registry, and in line with the overarching strategic priorities of the charity.

To work with partners to ensure data is used to enable people with CF to access safe, effective, and quality care, including informing and supporting research. This includes ensuring the patient-

centred, secure, transparent, and effective use of an enhanced Registry dataset to further research, service evaluation, pharmacoepidemiology and pharmacovigilance / post-marketing surveillance and the commissioning and reimbursement of high-quality clinical care.

Main Duties

Registry Operational Management

- Working closely with the Associate Director and Chairs of the UK CF Registry Steering Committee manage the Registry Team to ensure continued smooth operations of the Registry, including, but not limited to:
  - Monitoring and assurance of high-quality Registry data, including CF centre engagement and training and the Data Validation Programme
  - Leading and managing the relationship with external software developers Support major platform transformation initiatives.
  - Production of the UK CF Registry Annual Report
  - Running the UK CF Registry Annual Meeting
  - Registry-based studies and clinical trials
  - Management of the UK CF Registry Steering Committee
  - Annual submissions to NHS England commissioners
  - Submissions to NHS bodies responsible for monitoring the quality of clinical care, including but not limited to national programmes of care and the Quality Surveillance Team
  - Production of Payment by Results (PbR) tariff banding reports and payment of CF centre grants
- Role model a strong and collaborative leadership style, exemplifying the Trust's values.
- Lead and develop a strong team, which maximises the Trust's capacity to harness healthcare data for the benefit of people with CF, building and strengthening cross-team collaborations and partnership-working within the Trust.
- Support implementation of strategic changes to Registry processes, systems, and ways of working, ensuring smooth operational transition and minimal disruption to stakeholder services.
- Working closely with relevant team members, ensure operational continuity during periods of transformation, identifying and managing operational risks associated with strategic changes.

Information Governance and Secure Data Access

- Working closely with the Clinical Data Manager, lead the Registry Data Request Process, ensuring adherence to information governance, data security and ethical standards and:
  - Working with analytical colleagues, monitor KPIs and ensure key deliverables and timelines are met.

- Working with the Associate Director and Data Protection Officer, maintain awareness of the relevant regulations and standards and ensure these are applied to all relevant processes.
- Provide guidance and advice to external applicants on matters relating to our ethics approval, information governance and data confidentiality.

- Develop and maintain the Registry Quality Management System, including Registry Standard Operating Procedures (SOPs), Trust policies, and NHS ethical approval.

  - Be responsible for Registry SOPs, ensuring timely updates, implementation, and adherence across the team.
  - Ensure that Registry colleagues maintain appropriate training to undertake their roles, including data security, GDPR and Good Clinical Practice.
  - Have full awareness of the Registry Protocol, principles of informed consent and conditions of ethical approval, and ensure these are applied across all Registry workstreams.
  - Working with the Associate Director, maintain and renew the Registry ethical approval to ensure continued operation, supporting submission of substantial amendments when required.

- Working with internal colleagues, lead the annual submission to maintain the Registry NHS Data Security and Protection Toolkit accreditation, including implantation of current best practice data security standards.

- To recognise the need for and implement new and/or update policies and procedures as necessary.

Strategic Delivery and Stakeholder Engagement

- Support the implementation and delivery of the Trust's new UK CF Registry Health Data strategy.
- Support initiatives to coordinate enhanced data linkage capabilities with external datasets, including ensuring appropriate approvals and permissions are in place.
- Help broaden the reach and influence of the Annual Data Report and other Registry outputs, including working with analytical colleagues to improve and enhance data visualisations for public audiences.
- Work with the Director of Research and Healthcare Data and Associate Director to maintain and strengthen relationships with individuals working with the UK CF Registry and associated data.
- Support delivery of accessible communications, including public-facing materials and content for younger audiences.
- Work with CF centres and community stakeholders to strengthen understanding of the Registry's value and encourage high-quality participation.
- Ensure stakeholder feedback informs strategic and operational decisions as appropriate.

Finance, Contracting and Income Generation

- Working with the Associate Director, set and manage a budget comprising income and expenditure, working closely with the Finance team to ensure prompt and accurate payments and invoicing.

- Coordinate, manage and be responsible for our external Registry-based contracts, including those with pharmaceutical companies, NHS organisations, consultants, and other external stakeholders.
- Working with key colleagues establish processes to ensure timely negotiation and execution, invoicing, and reporting of deliverables.
- Support development and implementation of frameworks for commercial and non-commercial partnerships. Work with colleagues to ensure full cost recovery for registry-based studies and sustainable pricing approaches for both commercial and non-commercial partnerships and contracts.
- Working with the Business Development Manager and fundraising colleagues to proactively seek out opportunities to fund data related activity.
- Help develop relationships with funders, academic groups, NHS partners, and life sciences organisations to dive new opportunities and sustainability.
- Collaborate with other funding agencies, public or private, to ensure the UK CF Registry is properly represented in any research requiring access to the registry data.

Other Responsibilities

- Be an active member of the Trust's Senior Management Team, ensuring the Trust delivers and maintains an excellent service, in line with its strategy.
- Support colleagues across the Trust in their work with NHS commissioners and national programmes of care to ensure the CF Registry is recognized, valued, and utilised as a guiding resource for the management and care of people with cystic fibrosis.
- Work with team across the research and healthcare data directorate to promote and facilitate the use of the UK CF Registry for research, provide evidence for development of clinical guidelines, post-marketing surveillance, and clinical research.
- Be an ambassador for the Trust and UK CF Registry through engagement with external stakeholders including clinicians, academics, pharmaceutical companies, CF bodies, government organisations etc.
- Any other duties as required for the experience of the role.

This job description will be subject to review as required.

The Person Specification follows on the next page.

Person specification: Head of Registry Operations

Education and Qualifications	Essential	Desirable
Educated to degree level or equivalent in a relevant subject (e.g., science, medicine, statistics)	Essential	
Educated to postgraduate level in a relevant subject (e.g., science, medicine, statistics)		Desirable
Experience		
Experience of working with large observational datasets and/or clinical Registries, ideally with health data.	Essential	
Experience working with sensitive health data, information governance, or research governance frameworks.	Essential	
Experience of working in or with the National Health Service or comparable healthcare system	Essential	
Experience of managing multiple and complex projects	Essential	
Track record of positive relationship building leading to collaborative projects	Essential	
Experience of the design, set up and regulatory requirements of clinical trials and/or post-marketing surveillance	Essential	
Experience of maintaining operational excellence during periods of organisational change and change management	Essential	
Demonstrable experience of managing a multi-disciplinary team, with effective people and performance management	Essential	
Experience of managing software vendors and operational platform maintenance	Essential	
Experience of budget management and securing funding (ideally within a healthcare and/or charity setting)	Essential	
Experience of working in or with the charity sector		Desirable
Working in an academic research environment		Desirable
Work with industry, in particular the pharmaceutical industry		Desirable
Experience of software procurement		Desirable
Experience of linking datasets		Desirable

Experience working alongside strategy/transformation teams while maintaining operational delivery		Desirable
Knowledge		
Comprehensive understanding of data governance, and information security standards within a healthcare environment.	Essential	
Good understanding of clinical registries, research data infrastructure, or real-world evidence research	Essential	
Understanding of and commitment to equality, diversity, and inclusion	Essential	
Understanding of cystic fibrosis and our mission, values and goals	Essential	
Understanding of specialised services commissioning/NHS commissioning		Desirable
Understanding of health economics		Desirable
Understanding of Trusted Research Environments/ Secure Data Environments		Desirable
Skills		
Excellent written and verbal communication skills, and a confident public speaker	Essential	
Excellent interpersonal skills, and ability to act as an ambassador for the Cystic Fibrosis Trust	Essential	
Excellent organisational and time management skills to ensure timely delivery of reports, research calls and other documents as requested by the senior management team	Essential	
Collaborative team-player	Essential	
Tenacity, diplomacy, and attention to detail	Essential	
Self-motivated with the ability to prioritise in a complex environment	Essential	
Flexible and adaptable attitude to work and working practices	Essential	
Abilities		
Ability to work with a wide variety of stakeholders including people with cystic fibrosis and their families, academic research scientists, clinician scientists, senior members of other funding agencies including biopharmaceutical industry	Essential	
Ability to maintain operational excellence under pressure	Essential	
Personal resilience and ability to remain calm when managing complexity	Essential	
Ability to manage operational risk during periods of change		Desirable