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Belfast BT3 9DT
Northern Ireland

The CHQ Building
Custom House Quay
North Dock, Dublin 1

Cumulus Neuroscience – Clinical Trials Manager

At Cumulus Neuroscience, we develop cutting edge technologies for the measurement and interpretation of the progression of brain disorders.

Our machine-learning-powered digital health platform allows us to rapidly build the world's largest collection of real-world brain activity and cognitive health data. The insights we extract from this data help transform our understanding of brain health and improve the development of novel treatments for brain disorders.

Be part of an amazing team developing cutting edge tools to solve the biggest healthcare challenge of a generation.

We are expanding our team and are recruiting a **Clinical Trials Manager.** In this role you will report to the Director of Clinical Programmes and be responsible for successfully integrating new digital health technologies into health research and clinical trials targeting central nervous system (CNS) disorders.

Educated to degree level with previous clinical research and pharmaceutical/medical technology experience you will implement and oversee projects and ensure the quality of the trials. As Clinical Trial Manager you will collaborate with the Director of Clinical Programmes to review budgets, make changes where necessary, and outline projects together with our pharma partners and clinical staff monitoring the trial. You will be responsible for coordinating the set-up, conduct, and close-out of our rapidly expanding clinical trials portfolio.

We are seeking someone with experience in clinical trial management, who has a flexible approach and the ability to work as part of the team as well as independently. In addition, excellent communication, administrative and IT skills are required in order to support our business needs.

Key activities will include but are not limited to the following:

- As a key point of contact with external partners conducting research using the Cumulus platform, you will be expected to lead the day-to-day management and delivery of high-quality clinical research studies, both commercial and academic, working closely with site research staff and clinical research organisations (CROs)
- Supporting development and submission of ethics applications, interactions with MHRA and other competent authorities, and local site approvals
- Development and management of trial/study related documentation (protocol, CRF, Investigator Brochure, etc)
- Play an active role in study start-up, execution and close-out activities, ensuring all procedures are carried out in line with the protocol, standard operating procedures and all documentation approved by research ethics, and working in accordance with principles of Good Clinical Practice (GCP) and GDPR
- Proactively educate clinical staff in the specifics of running clinical trials in compliance with study protocols and according to Delegation of Duties
- Liaise with relevant bodies to set up funding and contracting to enable research to take place

- Ensure adherence to project milestones across multiple sites and be responsible for regular production of progress reports
- Coordinate and liaise with research ethics committees, local research governance, clinical staff, external subcontractors and internal multidisciplinary teams including regulatory affairs.

Required Criteria:

- Proven experience in working with clinical staff and leading training and development
- Experienced in research governance processes and able to demonstrate a clear understanding of clinical research, clinical trials and the regulations that govern them
- Experienced in instructing and managing external partners
- Recent training and experience working in accordance with GCP and GDPR principles
- Data management experience including planning and execution of clinical data management plans
- Ability to work as part of a multi-disciplinary, fast-paced diverse team
- Ability to interact with experts and non-experts alike
- Ability to work independently and prioritise duties
- Excellent communication, interpersonal, organisational and IT skills
- Ability to travel nationally and internationally as required to support on-going commercial engagements

Desired Criteria:

- Comfortable and experienced with electronic data capture: eConsent, eCRF, eCOA, eTMF
- Knowledge of and experience working with the MHRA and other competent authorities
- Relevant experience in the execution of studies using medical devices / digital health technologies
- Relevant experience working in populations with neurodegenerative or neuropsychiatric disease
- Experience in supporting development of commercial proposals for clinical trials and managing budgets

Minimum Qualifications:

- Undergraduate degree in a relevant life sciences area of study
- 8+ years' experience in commercial clinical research working at an investigator site, sponsor or CRO

Salary & Benefits:

- Competitive salary
- 25 days paid holidays
- Competitive benefits including pension match and private medical insurance

Location: Belfast, Northern Ireland
Interested candidates should send a CV and short cover email to info@cumulusneuro.com
Cumulus Neuroscience is an Equal Opportunity Employer.

We are not a licensed Visa sponsor and therefore can only consider applicants who independently meet UK Visa right to work conditions.