

# Senior/Clinical Research Associate – Role Summary

#### **About O4 Research**

O4 Research is a successful Clinical Research Organisation (CRO), providing clinical research solutions to the pharmaceutical, biotechnology, medical device and consumer health industries. We specialise in the strategic planning, set-up and conduct of Phase II-IV Clinical Trials and RWE/Non-Interventional Studies for our top 20 Pharma partners across the UK, Ireland and Europe.

Our multidisciplinary team of clinical research professionals thrive in the challenging, innovative and fulfilling nature of our work. Each member of our team is valued and actively contributes to the advancement of human health programmes across a wide spectrum of therapeutic areas, as together we incorporate our unique values into successful delivery of every study – open, original, obsessive, and always on your side. Our culture also enables significant opportunities for personal development and career advancement across clinical operations functions for every member of our team.

#### **About the Role**

O4 Research is recruiting for an experienced CRA/Senior CRA to join our growing team and work across a range of therapeutic areas for our commercial partners. At O4, we place the patient at the heart of our thinking and we are looking for like-minded individuals with a focus on delivering the best quality solutions for our clients through innovation and collaboration. As together, we seek to transform the future of clinical research for the benefit of us all.

This role offers a fantastic opportunity for professional success and development. By working directly with study specific Clinical Project Managers this role is ideally suited for experienced CRAs considering a transition into Clinical Project Management.

This Full/Part Time permanent position can be home or office based dependent on location of the successful candidate. An office-based appointment would involve working out of our headquarters in Belfast. The role offers a competitive package based on experience.

## **Key Role Responsibilities**

- Leverage your expertise by supporting the development of functional plans and conducting site visits including pre-study, initiation, monitoring and close-out visits. Monitor and review the integrity of the study against the protocol and ICH GCP standards.
- Put patients first by reviewing study performance at assigned sites, ensuring informed consent has been adequately performed conducted and verify compliance with Protocol and EDC requirements.
- Build relationships as the primary site contact for the study, promoting the development of
  effective working relationships with the site team and sponsor representatives.
- Full ownership of sites for assigned studies, performing site management activities through to close-out.
- Support ethics committee and regulatory submissions and approval, and site start-up activities through development of protocols and supporting documents.
- Provide mentoring, co-monitoring support and training for junior members of our team.
- Work closely with and provide support to the study Clinical Project Manager as required.
- Contribute to the continued success of O4 Research by actively enhancing role specific knowledge and sharing best-practice and suggestions with team members.



### Qualifications

### **Required Qualifications**

• BSc degree or equivalent is desirable, preferably in a Life Sciences discipline

## **Skills & Experience**

- A minimum of 1.5 years independent monitoring experience within a CRO or pharmaceutical environment
- Excellent written and verbal communication skills, interpersonal skills with ability to interact well and with diplomacy with all levels of management and staff (internal and external)
- Organisational and attention to detail skills with proven ability to prioritise workload/time management
- Demonstrate good IT and administrative skills, with the ability to work independently and cooperatively as part of a team, take initiative and complete tasks to deadlines
- Ability to take a patient centric approach to clinical research while ensuring sponsor study requirements are achieved. Have a results focused attitude, with a desire for success
- Demonstrated ability to resolve study-related problems
- Self-motivated, flexible and responsive to new ideas in a changing environment
- Approachable, personable and supportive of others with an open and transparent working style
- Ability and willingness to travel 50%+ of work time, a current full driving licence is essential
- Excellent understanding of ICH GCP, Regulatory and R&D Governance
- Experience in training, SOP implementation, EDC/web-based data collection and project tracking

If you would like to join a team of clinical research professionals who are seeking to transform healthcare and can offer opportunities for professional development within a fast paced and exciting environment, then we would like to hear from you. Please send your CV via the link provided or to careers@o4research.com.

Please note that due to the high volume of applications which we receive we will only be able to reply to candidates whom we are inviting for interview.

For Information visit <u>www.o4research.com</u>

Strictly no agency support services are required for this role