

Job Profile – Senior Clinical Research Associate

PART I - PROFILE

You are an experienced CRA with a strong background in Clinical Research who is passionate about drug development and are seeking a challenging and rewarding career in a quality focussed role. You will be looking to move into the challenge of complex and/or orphan indications in addition to working with Sponsors from Biotech and smaller Pharma Companies or start-up ventures.

We are differentiated in our market as an international, truly full service CRO, focussed on a series of core therapeutic disciplines. Simbec-Orion Group is an ambitious organisation with challenging growth targets both organically and through acquisition. You will be expected to take responsibility for monitoring clinical studies of new and established pharmaceuticals, ensuring that projects are conducted in accordance with the latest ICH guidelines. You will be responsible for all aspects of the study at sites and ensure that the Project Managers are kept fully informed of all aspects of the project. You will also ensure that project documentation is obtained and maintained in a timely manner

You will hold a degree in life sciences, ideally holding a role related MSc or PhD, you will have a proven track record as an accomplished CRA in IMP trials. You will have excellent communication and time management skills to manage multiple projects at any one time.

You are a strong team member and understand the need for effective communication at all levels. You will have a demonstrable record for effective relationship building with sponsors, sites and colleagues, as well as strong management skills.

You are confident in presenting studies at site. You have high standards for the quality of material presented.

Job Profile – Senior Clinical Research Associate

PART 2 – EXPERIENCE, QUALIFICATIONS AND ATTRIBUTES

The candidate will have:

- BSc degree in life sciences.
- 5 or more years monitoring in clinical research experience: experience in pharmaceutical or biotechnology companies but preferably in a CRO
- IMP trial experience is mandatory. Medical device experience and monitoring of non-IMP trials are not acceptable without recent IMP experience.
- Therapeutic area: Oncology experience is highly recommended. Other TA experience should ideally encompass complex indications and/or rare disease and/or trials in ICU settings.
- Current knowledge of ICH GCP
- Awareness of global regulatory and pharmacovigilance environments
- Fluent English. Local language is mandatory for positions outside the UK.
- Excellent communication skills, written, oral and presentation
- Excellent organisation and time management skills
- Proactivity and risk management skills
- Excellent computer skills
- Ability to drive

An ideal candidate may also have:

- An MSc or PhD in a related field
- Experience in EDC & CTMS
- Experience in site selection
- Experience in contracts negotiation
- Experience in EC & CAs submission preparation

PART 3 – JOB DESCRIPTION - JOB FUNCTION

1. Job Summary

- Administration and full investigator site responsibility for clinical studies according to ORION Standard Operating Procedures (SOPs), ICH-GCP and local regulations;

Job Profile – Senior Clinical Research Associate

- Acts as mentor for less experienced CRAs;
- May act as lead CRA assisting a Project Manager (PM);
- May act as lead CRA or as a PM of national studies;
- Ensures clinical trials are monitored such that subjects' rights, safety and well being are protected and that the clinical trial data are reliable.

2. Main Job Duties and Responsibilities

a. Clinical Trials

- Acts as a member of the project team with the goal to contribute towards efficient management of trials;
- Assists the PMs in the preparation and review of protocols and informed consent forms;
- Contributes to Case Report Form (CRF) design and clinical trial document development as they pertain to clinical monitoring activities (i.e. operating manuals, monitoring guidelines, etc.);
- Negotiates investigator budgets and assists with the execution of site contracts with support from the legal department;
- Involved in recruitment of potential Investigators, preparation of Independent Ethics Committee/ Independent Regulatory Board (IEC/IRB) submissions, notifications to regulatory authorities, translation of study related documentation, organisation of meetings and other tasks as instructed by the PM;
- Oversees all aspects of study site management to ensure high quality data resulting in consistently low query levels and in good Quality Assurance reports;
- Establishes, updates, tracks and maintains study specific trial management tools/systems, and status reports;
- Performs pre study visits: discusses protocol, other available study documentation and study requirements with Investigator and other trial staff, ensures that trial staff and site facilities and the site's recruitment potential are in accordance with protocol requirements, local regulations, ICH-GCP and ORION SOPs;
- Performs initiation visits: trains Investigators and other trial staff in the protocol and data collection methods to ensure collection of patient data is accurate, complete, and conforms to protocol requirements, in accordance with local regulations, ICH-GCP and ORION SOPs;
- Performs monitoring visits: ensures adherence to protocol, accurate data collection via comprehensive source document verification, and investigational product/biological samples/supplies accountability;
- Communicates effectively with site personnel, including the Principal Investigator (PI), and ORION management to relay protocol/study deviations and ensure timely implementation of corrective actions;
- Develops and maintains strong working relationship with Investigators and study staff, serving as an ambassador to promote ORION's high quality and ethical image;
- Maintains study tracking, in accordance with the demands of the study;

Job Profile – Senior Clinical Research Associate

- Understands and updates Clinical Trial Management System (CTMS) in a timely manner;
- Monitors and updates data in an Electronic Data Capture (EDC) system in a timely manner and in accordance with study specific guidelines;
- Performs data management review, including in-house CRF review, and alerts project managers and data managers to emerging issues with CRF completion;
- Identifies and processes Serious Adverse Events (SAEs) according to the procedures defined by the study team;
- Demonstrates a broad understanding of the SAE reporting process to regulatory authorities;
- Liaises with data management to resolve data discrepancies and ensure all data management study goals are met;
- Prepares and performs closeout visits according to the protocol, local laws, ICH-GCP and ORION SOPs;
- Prepares accurate and timely visit reports from all types of visits;
- Functions as a mentor, assisting with the training and developing of less experienced CRAs via shadow or co-monitoring visits;
- May be involved in preparation of status reports for clients;
- Conducts feasibility work;
- Assists in business development;
- Interacts with internal work groups to evaluate needs, resources and timelines;
- Initiates payment requests for Investigators;
- Develops SOPs when required;
- Assumes project management responsibility as needed;
- Performs other duties as assigned by management;
- Travels as necessary according to project needs.

b. Management of other CRAs

Management of Administrative Aspects

Responsibility for all of the following administrative aspects according to ORION SOPs:

- Ensures that each new CRA undergoes induction and that the induction was successful and productive;
- Verifies that *curriculum vitae* (CV), job description and training records are complete and current for Human Resources (HR) files;
- Reviews and authorises AREA (timesheets) and reviews monthly and weekly activities to assess the workload of CRAs;
- Reviews and authorises CRA expense reports in accordance with company and project guidelines;
- Validates travel and hotel requisition forms if delegated;

Job Profile – Senior Clinical Research Associate

- Ensures annual leave and sick leave are approved and taken in accordance with company guidelines.

Monitoring and Performance Assessment

- Organises meetings with reporting CRAs in order to conduct two-way feedback focused on development and goal-setting (at least every 3 months);
- Performs objective setting and annual appraisals of reporting CRAs;
- Interacts with PMs to ensure optimal CRA management and support;
- Performs accompanied visits according to applicable ORION guidelines;
- Performs ad hoc quality review of visit reports for each CRA and gives feedback of any issues to both CRA and management;
- Identifies any performance problems of CRAs and ensures that a corrective action is undertaken (training, etc.);
- Reinforces to CRAs the correct application of ICH-GCP and provides training as appropriate;
- Estimates workload of CRAs and alerts the Director of Clinical Operations in the event of problems relating to internal staff workload that may affect the quality and functioning of the studies being undertaken;
- Is involved in the career coaching and progression of CRAs;
- Is involved in the finding of solutions to bonus, salary or promotion issues;
- Motivates CRAs and encourages them to be efficient and proactive;
- Helps CRAs to optimise their daily functioning by sharing with them successful monitoring and task management approaches.

PART 4 – BACKGROUND TO SIMBEC-ORION

Simbec-Orion Group Limited (“Simbec-Orion” or the “Group”) was created in June 2014 by the merger of Simbec Research Limited (“Simbec”) and Orion Clinical Services Limited (“Orion”).

As a result of the merger, Simbec-Orion is today a full service CRO covering first in human Phase I clinical studies through to pivotal Phase III studies and Phase IV post marketing studies. Simbec-Orion supports its clients with our own in-house full service central laboratories, pharmacovigilance, data management and statistics, IMP management/pharmacy, medical management. We have expertise in all drug types, dosage forms and delivery mechanisms and in later stage development and have six core therapeutic disciplines:

- oncology,
- rare and orphan diseases,

Job Profile – Senior Clinical Research Associate

- respiratory disorders,
- dermatology,
- infectious disease & vaccines, and
- translational medicine.

We operate internationally serving clients anywhere in the world with physical operations in the United Kingdom, France, Germany, Italy, Spain, Czech Republic, Poland, Australia, South Africa and the United States of America. We have a combined staff approaching 250 people with the greatest concentrations in the UK and France.

It is our objective to become widely recognised as being a significant international full service CRO known for its excellence both across its range of services and in its therapeutic disciplines. We compete effectively against many of our larger competitors by offering a broader range of services and with greater depth of knowledge in our chosen therapeutic areas.

Given the background of a number of our senior leadership team, we think with the same focus as our clients - as drug developers and not simply as outsource service providers. Our goal is to meet their actual needs and not simply execute a study.

Our growth targets aim to see the Group grow from its current size of approximately revenues of £25m (\$37m) per annum to £100m (\$150m). This will be achieved in part by organic growth but also through further M&A activity.