



Nexus Oncology

## Job Description

Job Title: Senior Clinical Research Associate  
Reporting to: Clinical Operations Director

### Job Purpose

- To take the Lead Clinical Research Associate (CRA) role as required, liaising between the (Project Manager) PM and CRA team
- To deputise for the PM during periods of absence of the PM
- To co-monitor with members of the CRA team as required
- To track key project deliverables as delegated by the PM
- To represent Nexus Oncology at meetings with ongoing clients
- To ensure data quality at study sites for which CRA is responsible
- To ensure compliance with protocol at site for which CRA is responsible
- To ensure compliance of the sites for which the CRA is responsible with relevant SOPs and regulations

### Main Tasks

- To work with Nexus management (CEO and Business Development representative) when new project contracts are being negotiated in order to provide feedback about feasibility and optimum project conduct including recommending sites and countries
- To arrange, or help with the arrangement of, project kick-off meetings (if budgeted for in the contract with the sponsor) to ensure all relevant team members are clear about the scope of work including provision of project specific information, provision of clear timeline expectations, provision of all relevant procedures to follow and provision of clear instructions about communication and documentation. In addition, other information that is relevant for study progress should be shared with the project team at this meeting
- To conduct, or help with the conduct of, ongoing project team meetings (either face to face meetings or teleconferences, depending on the location of the team members) in order to monitor study progress and address any issues raised by the project team. At such meetings, the project team members will be given instructions regarding project priorities and tasks that the project team members need to undertake in order to conduct the study and facilitate progress
- To attend Project Team meetings with the sponsor as required
- To establish ongoing priorities with the sponsor as required
- To understand the product, protocol and therapeutic area in sufficient detail to be able to advise and discuss with the CRA Team and study site personnel
- To conduct site selection activities including attendance at site selection visits
- To prepare ethics submissions
- To provide assistance with regulatory submissions
- To prepare or assist with the preparation of investigator contracts
- To write or review protocols
- To write or review case report forms

- To conduct Site Initiation Visits where all relevant training will be given including, but not limited to, the protocol and protocol procedures, the information and consent process, SAE reporting, sample processing and shipment and drug handling and accounting.
- To monitor study sites for which the CRA is responsible. This includes but is not limited to checking drug supplies, checking site compliance with protocol and all current and relevant regulations, conducting source data verification, ensuring all serious adverse events (SAEs) have been reported appropriately and providing written follow-up requests to the site in order to correct any issues identified at the monitoring visit
- To monitor patient recruitment timelines at sites for which CRA is responsible and report this information to the PM
- To report all relevant safety information to the PM from the sites for which CRA is responsible
- To check the study file periodically to ensure compliance with relevant SOPs and regulations
- To conduct ongoing CRF discrepancy resolution
- To inform PM and sponsor of any protocol violations
- To monitor study drug requirement at sites for which the CRA is responsible and notify project manager and/or sponsor when additional supplies need to be shipped to the site
- To monitor SAE reporting by the site
- To comply with Nexus obligations regarding reporting of SAEs to the sponsor
- To perform site close-out visits
- To document all study site visits including selection, initiation, monitoring and close-out visits
- To provide information about patient recruitment, site status, discrepancy resolution, SAE status and other important information to the PM as requested, regarding sites for which the CRA is responsible
- To write or review study reports
- To remain up to date with all relevant SOPs and regulatory requirements, and developments in the relevant therapeutic area/s.
- Training and sharing of experience with less experienced team members

This list of tasks is not exhaustive. The post holder may be asked to perform additional appropriate tasks depending on the demands of the service.