Position Description
Clinical Research Associate

Improving the treatment and the lives of patients with blood cancers through clinical trial research

Job title	Clinical Research Associate
Location	ALLG Clinical Trial Centre, Richmond
Reporting to	Direct: ALLG Program Manager Indirect: ALLG Business Manager, ALLG CEO
Main purpose of position	**Central coordination and data management of allocated ALLG clinical trials**
Key Effectiveness Areas	• Coordinate the steps which facilitate and streamline the activation and management of allocated ALLG clinical trials. • Develop and/or maintain resources to support clinical trials, such as tracking logs, study manuals, Trial Master File (TMF) • Data management including case report forms (CRF) design, data management plan (DMP), data entry, queries and cleaning, data reconciliation, quality control of database • Support the conduct of allocated clinical trials through effective communication with the ALLG team fostering collaboration with ALLG investigators • Assist with the development and project management infrastructure and provide support for the ALLG Clinical Trial Centre
Key Relationships	**Internal:** ALLG senior Clinical Research Associate ALLG Operations Unit staff, including Protocol Development Coordinator ALLG Clinical Trial Centre staff Clinical trial PI and site staff ALLG Biobanking coordinator

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	Members of the ALLG Scientific Advisory Committee Statisticians **External:** Pharmaceutical company representatives External service providers Key industry partners and professional associations
Key Selection Criteria	**Essential** • Tertiary qualification in a health or science field • Experience in clinical research and data management • Demonstrated understanding of Good Clinical Practice (GCP), regulatory, ethical, privacy and other relevant guidelines • Understanding of medical terminology, ideally oncology, haematology • Experience in Case Report Form (CRF) design • Excellent organizational skills including the ability to establish and work within timelines • Demonstrated experience with Microsoft Word, Outlook, Excel, PowerPoint • Demonstrated project management skills including the ability to work autonomously across multiple projects with tight timelines • High attention to detail • Ability to review processes and suggest improvements to enhance existing methods • Excellent oral and written communication skills • Personal confidence and demonstrated ability to liaise with professionals from a variety of backgrounds • Able to work independently and as an effective member of a multi-disciplinary team • Willingness to travel interstate as required

	Desirable • Experience in data entry • Experience with Microsoft Access • Experience with InDesign or other desktop publishing software • Experience in Standard Operating Procedure (SOP) preparation and application of SOP's in daily trial conduct • Experience with multi-site trials • Experience with eDC systems

Performance Objectives	**Key Performance Indicators**
1. Coordinate the steps which facilitate and streamline the activation and management of allocated ALLG clinical trials. Develop and maintain resources to support clinical trials, such as registration and randomisation procedures, tracking logs, study manuals, TMF.	• Documented timely activation of multi-centre trials, with expression of interest (EOI) forms, site initiation visits (SIV) and site activations performed as per project schedule • Preparation of study manuals within study activation timelines • Set up and maintain applicable tracking logs (e.g. for EOIs) and TMF • Maintain study drug supply • Ensure regular communication, via websites and email lists, with participating sites and the appropriate professional staff at those sites – evidence of appropriate communication • All project files up to date and accessible at all times • Evidence that knowledge of SOPs has been developed and that the appropriate operating procedures (e.g. ALLG SOPs) for the coordination of trials that are consistent with GCP, have been followed in each trial from commencement to close out • Maintenance of GCP standards in all clinical trial activities • Feedback indicating effective presentations at SIV and trial group meetings. • Fulfillment of regulatory reporting requirements within appropriate timelines • Up to date trial registry (ANZCTR) listing • Preparation of reports for periodic review by ALLG Safety and Data Management Committee (SDMC), other applicable data and

	safety monitoring boards or trial management committees
2. Data management including CRF design, data management plan (DMP), data entry, queries and cleaning, data reconciliation, quality control of database	• Design of CRF (paper or electronic as required) to capture all information relevant to trial outcomes (where applicable to trial) • Prepare and implement data management plan (DMP) within appropriate study timelines • Register all patients in trial database within 24 hours of receipt of notification of registration • Data, particularly data related to safety monitoring, to be entered in a timely and accurate manner and data extracts prepared to ensure that SDMCs can operate • Trial databases to be regularly maintained with data entry current, and routinely checked for consistency – evidence of up to date data entry and regular quality assurance • Data cleaned and suitably queried within appropriate timelines • Timely calls for CRFs, maintenance of tracking logs for CRF return and data queries, and persistent follow-up of slow responders • Assist the PI, statistician and research team to achieve analysis and publication of data • Achieve proficiency in data entry for particular clinical trials as evidenced by data entry accuracy checks
3. Assist with the development and project management infrastructure and provide support for the ALLG Clinical Trial Centre	• Undertake training in relevant ALLG SOPs • Preparation and/or review of SOPs • Identify potential for, assist with review and undertake improvements in clinical trial process as approved by Clinical Trial Program Manager (e.g. electronic CRF systems) • Minute meetings and other events as required • Assist the Clinical Trial Program Manager in organising aspects of the ALLG clinical trial portfolio • Supervise other trial support staff as delegated by the Program Manager or senior CRA within the ALLG Clinical Trial Centre • Provide backup on non-allocated ALLG clinical trials as per roster and directive of line manager

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4. Professional and personal development. Takes an active role in ALLG scientific meetings. Attends relevant educational/professional forums	• Professional development is maintained and promoted • Attends and takes an active role in ALLG scientific meetings (appropriate feedback received) • Acts in accordance with hospital policies • Assists in the development of appropriate quality activities
5. Other duties	• Perform other duties as required to a satisfactory standard.