Position Description
Clinical Trial Assistant

Job title	**Clinical Trial Assistant**
Location	ALLG Clinical Trial Centre
Reporting to	ALLG Senior Clinical Research Associate ALLG Program Manager
Main purpose of position	To support data management project activities according to and within pre-defined timelines
Key Effectiveness Areas	• Provide high level support to the trial program to ensure objectives are met • Observe and role-model the use of ALLG Policy and Procedures, and SOPs in all activities. Contribute to quality assurance activities and internal auditing for compliance as needed • Support all aspects of Data management activities on a clinical trial from stages of protocol review to the final data deliverable to the CI • Clear demonstration of the ability to manage multiple projects with different timeline demands. • Assist with Trial Master File management. • Work collaboratively and takes direction as required from the Program Manager, Data Manager, sCRAs, CRAs and other CTAs to meet project deliverables and timelines.
Key Relationships	Internal: ALLG CEO, Clinical Trial Chief Investigators, Principal Investigators, ALLG Operations Unit staff and Trial Centre staff External: Biostatistician, Consumer groups, collegial organisations
Key Selection Criteria	Essential • Tertiary qualification, or progress towards tertiary qualification, in a health or science field • Experience in data entry or management of data • High level of proficiency with computer software including MS Office suite, MS Access, Adobe Acrobat • Effective communication skills, verbal and written • Experience working with detailed information • Ability to multitask under tight deadlines and prioritise work • High attention to detail • Ability to problem solve and work autonomously, but seek direction when required.

	• Willingness to travel interstate as required (minimal travel) **Desirable** • Understanding of medical terminology, ideally oncology, haematology • Experience in electronic data capture systems • Experience in clinical trials, especially clinical trial data • Demonstrated understanding of Good Clinical Practice, ethical and privacy guidelines and applicable industry standards in data management • Familiarity with clinical trial protocol design and statistical concepts

Performance Objectives	Key Performance Indicators
1. Provide high level support to the ALLG trials to ensure objectives are implemented	• Draft documents or otherwise assist with document preparation, including meeting and policy documents • Demonstrated adherence to GCP, privacy and data management standards and ALLG Trial Centre SOPs • Other high level contribution or activities as requested
2. Oversight, contribute and provide support to activities related to ALLG trials	• Assist with issues relating to on-going or closed trials as requested, (e.g liaison with international sponsors, liaison with ALLG site HRECs, archiving etc) • Provide summary data as requested for internal reporting or for ALLG contributions to meta-analyses and other external approved studies • Perform data entry ensuring quality, accuracy, completeness and integrity of clinical data • Review clinical data as required by data cleaning plans and generate queries as directed to investigator sites. • Collaborate with investigator sites and CRAs to resolve data issues and ensure timely data entry and query resolution • Recommend corrective action for data handling issues • Perform reconciliation of non-CRF data with CRF data • Drive problem solving with sites, sponsors, statisticians, and other team members to ensure all data review issues are resolved. This includes identification of the problem, identifying the solution, consulting management as required and coordinating the execution of the

	solutions. • Responsible for ensuring adherence to the Data Management Plan for all data quality activities • Contribute to the establishment of study timelines and milestones • Report status of data and data issues to the project team. Escalate issues appropriately • Develop CRF Completion Guidelines and obtain appropriate approvals. • Maintenance of trial TMF
3. Create and maintain project documentation relevant to data management activities	• Keep management abreast of issues and progress on all assigned projects • Keep SCRA and CRA informed of any data issues or cleaning status on all assigned projects • Create documents to monitor edit checks performed where required • Maintain tracking system for incoming CRF paper data as required. • Other duties as assigned including but not limited to User Acceptance Testing (UAT) support, scanning and filing of essential documents for trial archives • Identify and report any database/eCRF problems. • Assist in the planning and implementation of clinical data management processes.
4. Oversight, contribute and provide support to ALLG Trial Centre and ALLG PIs in relation to activities related to ongoing trials	On a trial by trial basis and upon request • Minute taking • Liaison with site staff, particularly with requesting submission of data
5. Other duties	• Mentor and train new and/or junior data staff as requested • Contribute to internal process development and improvement • Perform other duties as required to a satisfactory standard.