Position: CRA

Department	Clinical Trials
Basic qualification required	B.Pharm / M. Pharm, M.Sc, Pharm D
Brief JDs	**Job Description :** • Identify and qualify potential investigators to ensure that the sites have adequate time and can fulfill their obligation to the study. • To review research protocols and amendments, informed consent documents, case report form and/or other applicable business and project related documents to provide the feedback for modification/alterations if any. • Responsible for identification & collection of necessary documents to be forwarded to Project Manager/ designee, in order to check the feasibility of site/ investigator and approval from authorities. • Prepare or submit or support other colleagues for Regulatory and EC submissions and in the generation of Financial Agreements according to standard and local country practices. • Negotiate study budgets with investigators and ensure that timely payments are made to the site as per guidance from Project Manager. • Responsible for training of site study team regarding the monitoring plan, recording & maintenance of essential documents and for start up activities & site initiation as per guidance of Project Manager. • Assist for the preparation and presentation at investigator meetings, as required to ensure that the clinical and investigational site staff team are well informed about the study and related procedures. • Conduct of monitoring visits as per monitoring plan in order to check compliance with study management, protocol & other requirements at all assigned sites. • Maintaining a working copy of Central Investigator File & ensuring consistency with the Site Investigator File in order to maintain a working record of all essential documents and reports. • Perform source document verification as per monitoring plan and ensure that source documents & other trial records are

	accurate, complete, kept up-to-date & maintained according to applicable SOP's to avoid incomplete records. • Ensure timely collection of documents like CRF, DCFs etc from the site along with SAE reports in order to provide Biometrics/licensing authority & others with the necessary documentation and within required timelines. • Responsible for study updates & Coordination with Labs & other trial related services as per the study requirements. • Responsible for IP accountability and availability, tracking and management of all Clinical Trial related supplies shipped to the sites/ warehouse & accordingly clinical trials supplies vendor management for the study. • Ensure proper escalation of site/project related issues to Project Manager/ Designee on timely manner. • Ensure issue management at site level/ vendor level in coordination with PM. **JOB DESCRIPTION** **Confidential Page 2 of 2** • Responsible for site-closeout & follow up activities in order to maintain documents at the site. • As CRA, manage and monitor time budgeting, incorporating revenue recognition, to ensure that any potential cost over-runs are identified and addressed at an early stage. • Coordinate with team/ other CRAs to provide study status updates to the Project Manager and client as per the requirements. • Evaluates the speed of recruitment and propose alternative solutions if the predefined objectives are not met, either in the terms of patient number or timelines. • To liaise with other departments within the organization for timely achievement of the project milestones. • Attend staff meetings and training sessions as required to complete the training curriculum in a timely manner. • Assist with the audit of an investigational site or central files and liaise with Quality Assurance personnel as required to ensure that the study is being conducted in accordance with ICH GCP and other applicable regulatory guidelines. • Ensure to follow and adherence of organization's general rules, policies and applicable SOPs. • Provide feedback on SOPs, procedures and practices for maintenance and to make them user friendly. • To coordinate with training department/ designee for training initiatives to CRA/CTA as applicable.

	• To meet or exceed the planned metrics and expectations of sponsors/team/project manager.