Clinical Research Associate II – Clinical Trial

Department	Clinical Trials
Designation	Clinical Research Associate II
Basic qualification required	B. Pharm / M. Pharm / M. Sc.
Experience	2 - 4 Years – Site monitoring
Location	Ahmedabad
Brief JD	1. Identify and qualify potential investigators to ensure that the sites have adequate time and can fulfill their obligation to the study. 2. 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. 3. 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. 4. Negotiate study budgets with investigators and ensure that timely payments are made to the site as per guidance from Project Manager. 5. 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 the guidance of Project Manager. 6. 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. 7. Conduct of monitoring visits as per monitoring plan in order to check compliance with study management, protocol & other requirements at all assigned sites. 8. 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. 9. 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. 10. Ensure timely collection of documents like CRF, DCF etc from the site along with SAE reports in order to provide Biometrics/licensing authority & others with the necessary documents. 11. Responsible for study updates & Coordination with Labs & other trial related services as per the study requirements. 12. 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. 13. Ensure proper escalation of site/project related issues to Project Manager/ Designee on timely manner.

	14. Responsible for site-closeout & follow up activities in order to maintain documents at the site. 15. Attend staff meetings and training sessions as required to complete the training curriculum in a timely manner. 16. Assist with the audit of an investigational site or central files and liase with Quality Assurance personnel as required to ensure that the study is being conducted in accordance with ICH GCP and applicable regulatory guidelines. 17. To liaise with other departments within the organization for timely achievement of the project milestones. 18. Ensure to follow and adherence of organization's general rules, policies and applicable SOPs.

Interested candidates can send their resume at **apurohit@cliantha.com**