



In-House Clinical Research Associate (CRA)/ Clinical Trial Assistant (CTA)/ Project Associate (PA):

Department	Clinical Trial Dept.
Designation	CRA
Basic qualification required	Science Graduate
Experience	2-4 Years
Location	USA
Brief JD	<ol style="list-style-type: none"> 1. 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. 2. 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. 3. Conduct of co-monitoring visits as per monitoring plan in order to check compliance with study management, protocol & other requirements at all assigned sites. 4. Management of training of site study team regarding the monitoring plan, recording & maintenance of essential documents and for startup activities & site initiation as per the guidance of Project Manager. 5. 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. 6. 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. 7. Responsible for assisting site monitor for 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 SOPs to avoid incomplete records. 8. 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. 9. Responsible for study updates & Coordination with Labs & other trial



related services as per the study requirements.

10. Responsible for assisting site monitor 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.
11. Ensure proper escalation of site/project related issues to Project Manager/ Designee on timely manner.
12. Responsible for assisting site monitor for site-closeout & follow up activities in order to maintain documents at the site.
13. Attend staff meetings and training sessions as required to complete the training curriculum in a timely manner.
14. 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 applicable regulatory guidelines.
15. To liaise with other departments within the organization for timely achievement of the project milestones.
16. Ensure to follow and adherence of organizations general rules, policies and applicable SOPs.

Any Additional responsibility given by Head of the Department / Management