



### Team Lead – Central Monitoring

Department	Clinical Trial
Designation	Team Lead
Basic qualification required	B.Pharm / M.Pharm / M.Sc
Experience	7 - 9 Years
Location	Ahmedabad
Brief JD	<ol style="list-style-type: none"> <li>1) Provide oversight on central monitoring deliverable on assigned projects as per the protocol, SOPs, respective regulation/guidelines and project Central Monitoring Plan (CMP) from Applications/ Analytics/ Therapeutics/ Quality perspective.</li> <li>2) Contribute and/or oversee to the development and use of study management plans, specific tools and document templates and/or other study specific plans to evaluate the quality and integrity of the study.</li> <li>3) Support project management team to develop monitoring strategy including monitoring triggers/thresholds.</li> <li>4) Manage and monitor operational insight of the assigned project (s) and complete/oversee the study/site metrics trending (trend analysis of clinical aspects of the trial share trends and agree on action plan, review, triage and action clinical study alerts, monitor central monitoring plan (CMP) compliance etc.</li> <li>5) Contribute to developing the study specific central monitoring plan, analytics strategy and work on developing advanced analytics.</li> <li>6) Provide Inputs to clinical study teams, key decision makers, and internal team members to manage continuous process improvements, issue escalation, workload projections.</li> <li>7) Conduct periodic review of site level KRIs and historic site performance per Central Monitoring Plan (CMP).</li> <li>8) Early identification of site-level risk/issue(s) occurring during study conduct and responsible for identification of risk.</li> <li>9) Evaluate the quality and integrity of study site practices related to the proper conduct of the protocol and adherence to applicable regulations.</li> <li>10) Monitor site performance and make recommendations for timely corrective actions (e.g. Site Telephone Contact or Triggered Onsite Monitoring Visit).</li> <li>11) Monitor operational triggers/Key Data Points/data trends and</li> </ol>



monitor their compliance check by performing regular Quality Check.  
12) Support the Centralised Monitoring Advisor/Centralised Monitoring Manager in periodic review of Centralised monitoring training and/or identify the training needs of the team and provide inputs whenever required.

Interested candidates can send their resume at [rhourey@cliantha.com](mailto:rhourey@cliantha.com)