Position: Lead Clinical Research Associate

JOB DESCRIPTION:

Responsible for overseeing team of Clinical Research Associates (CRA) who provide qualification, selection, monitoring, and close out of sites performing clinical trial(s) as well as monitor's sites on behalf of Heron Therapeutics, Inc. Reviews work load requirements and provides resourcing for all clinical field activities. Ensures that staff perform their duties in line with the Code of Federal Regulations (CFR) of the Food and Drug Administration (FDA) and the International Conference on Harmonisation - Good Clinical Practice (ICH-GCP).

ESSENTIAL DUTIES & RESPONSIBILITIES:

- Evaluate clinical trial resourcing requirements for qualification, training, monitoring and support of sites during the conduct of the trials. The resourcing plan must balance the cost of travel within geographies with expertise within available resources.
- Develop a monitoring plan for each clinical trial.
- Hire and train monitors (CRAs) and other clinical trial support staff (CTAs). Ensure the monitors are adequately trained on the therapeutic area and study and are prepared to train the site staff during the Site Initiation Visit (SIV) and at other times to trial-specific industry standards.
- Liaise with doctors/consultants or investigators conducting the trial as required to insure that monitors are meeting expectations.
- Oversee the setup of the trial sites; ensuring each site has the appropriate trial materials to conduct the study.
- Oversee site activation process for each study.
- Develop and monitor metrics to evaluate the monitor and site performance. In the event of performance concerns, evaluate cause and mitigate risk to study.
- Periodically review data to identify potential issues or inconsistencies that could signal problems with data collection or monitoring.
- Track patient enrollment and recommend solutions to monitoring staff to increase appropriate enrollment of qualified subjects.
- Provide support for the processing of data queries.
- Review and approve monitoring visit reports.
- Develop and execute a plan to close trial sites on completion of the trial and perform associated close-out activities.
- Ensure adherence to GCP, Standard Operating Procedures (SOPs) and study protocols.
- Ensure monitors are providing for regulatory compliance of investigational sites with Heron Therapeutics SOPs, FDA regulations, and ICH guidelines.
- Coordinate data management activities.
- Co-monitor as required to provide coaching and manage performance of CRAs.
- Generate protocol Informed Consent template.
- Review site Informed Consent forms and site related materials as needed.

- May prepare study documents such as the Monitoring Manual, Study Operations Manual, Source Data Verification Plan, Laboratory Manual, Pharmacovigilance Plan, and Informed Consents.
- Assist with protocol development and study report completion.
- Assist with CRF development.
- Plan and participate in investigator meetings.

REQUIREMENTS:

- Bachelor's degree (BA/BS) or nursing degree (associate of applied science or above). Clinical research or life science degree preferred. Advanced degree is preferred.
- Certified as a CRA, e.g. CCRA, CCRP, or other CRA certification strongly preferred.
- Seven or more years of relevant experience with at least two years of experience in a pharmaceutical/biotech company.
- Prior supervisory or study management experience.
- Demonstrated working knowledge of GCP, ICH guidelines, and FDA regulations.
- Demonstrated ability to work independently and in a team environment.
- Proficiency with MS Office.
- Excellent oral and written communication skills and strong organizational abilities.
- Ability and willingness to travel 25% - 50% of the time (internationally and domestically).

The above description is intended to describe the general nature of the job and may include other duties as assumed or assigned; it is not intended to be all inclusive or limit the duties of the position.

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