HERON THERAPEUTICS

POSITION: Senior Manager, Clinical Operations (Oncology)

JOB DESCRIPTION:

Independently manages multiple global clinical trials of moderate to high complexity. Expected to manage all sites and vendor (e.g. Clinical Research Organization) related issues, with supervision from the Director/Sr Director/VP Clinical Operations. Simultaneously manages all aspects of multiple global clinical studies (Phase I through IV).

ESSENTIAL DUTIES & RESPONSIBILITIES:

- Manages study operational plan and CRO activities, including project timelines & quality of deliverables, and managing approved trial budget(s) throughout the life of the assigned clinical trial(s).
- Participates in the selection of study vendors for assigned studies.
- Maintains frequent and meaningful contact with CROs to assess performance and provide guidance as needed.
- Reviews and refines clinical operational plans including the study monitoring plan and other plans as needed.
- Coordinates internal and external clinical development activities of all team members involved in the design and conduct of assigned clinical trials.
- Contributes to relevant study documentation including clinical protocols, statistical analysis plan, clinical study reports as well as operational plans (CMP, DMP).
- Develop and manage study timelines (including recruitment) and may develop and manage program timelines.
- Participates in the selection of investigational sites with input from Clinical Research and vendors.
- Assists with medical issue resolution.
- Proactively identifies project risks and resolves with some supervision.
- Participates in study data review and other review activities as assigned.
- Oversees clinical trial sites' adherence to pertinent regulations through review of monitoring reports, CQA-GCP audit report, communications with investigators, study site personnel, CRAs, and other CRO/designee personnel.
- Leads ongoing review of data to ensure GCP.
- Oversees the submission of trial-related and essential documents to the Trial Master File.
- Identifies and provides solutions to clinical trial issues and/or risks.
- Represents Clinical Operations in cross-functional initiatives, as assigned by management, and may act on behalf of team when designated.
- Provide or facilitate training to clinical study teams on assigned protocol specific topics.
- Work closely with other teams in the organization, e.g. quality, regulatory, etc.

- Provide input into non-project related activities and development of department processes, procedures, and guidelines as requested.
- Assists with development of clinical protocols and other documents (i.e., ICDs, CRFs, SOPs, etc.)

REQUIREMENTS:

- BS or Master's Degree in nursing, life science, or related field (or equivalent experience).
- Minimum of 10 years of clinical research experience, at least 5 of which are as a project manager for clinical studies at a CRO and/or pharmaceutical/biotech organization with increasing demonstration of independence and sound judgement.
- Demonstrated ability to exercise judgement within broadly defined practices and processes.
- Previous experience negotiating vendor/site contracts and managing the budgets.
- Thorough understanding of FDA, ICH and GCP guidelines.
- Experience with Phase I – IV clinical trials.
- Proven track record showing clear proficiency in clinical project management skills.
- Proven complex problem solving skills.
- Solid vendor management skills, e.g. CRO, Laboratory & Clinical supply logistics.
- Broad understanding of clinical operations related to clinical development functions.
- Detailed understanding of all aspects of clinical protocol design and implementation & overall drug development.
- Ability to effectively interface with medical personnel at clinical site(s).
- Ability to lead multi-disciplinary, cross-functional teams both internally & externally.
- Ability to write and edit technical documents, such as protocols, protocol amendments, informed consent, and other trial-related documents.
- Detail and team oriented with excellent cross-functional team leadership and participation skills.
- Excellent interpersonal, verbal and written communication skills are essential in this collaborative work environment.
- Proficiency with computer programs including Microsoft Office suite and Microsoft Project.
- Ability and willingness to travel 10-15% of the time (internationally and domestically).

The above description is intended to describe the general nature of the job that 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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