Director, Clinical Science

Remote

Summary

Reporting to the Chief Medical Officer (CMO), the Director, Clinical Science will be a key contributor to Sierra's clinical development programs. The Director, Clinical Science is responsible for scientific leadership for the planning and execution of clinical studies in order to successfully move programs through the clinical research process in a timely manner, in adherence with GCP, appropriate SOP's and government regulations.

Responsibilities

- Under the direction and oversight of the CMO, design, oversee and/or execute, as needed and as appropriate key clinical deliverables including document development (INDs, Protocols, ICFs, IBs, Regulatory packages, etc.), medical and scientific input into the development of deliverables required for study activation and study conduct (CRFs, SAP, Data listings, etc.), data review process, and other deliverable as needed.
- Contribute medical and scientific input into the Clinical Development Plans for preclinical and early stage clinical assets.
- Identify risks, develop risk mitigation plans, and escalate risk mitigation strategies as appropriate.
- Contribute to and optimize an effective KOL and investigator communication strategy, interacting with investigators as warranted to obtain necessary information before, during and after the study.
- Working with other departments, create functional policies and procedures to provide strong and efficient clinical development processes that are appropriate for a matrixed environment.
- Ensure that SOPs are current and complete.
- Assess, recommend, track functional budgetary and staffing needs for medical/clinical aspects of clinical trials, as aligned with the Sierra operating model for Development and associated activities.
- Work closely with individuals in other functional areas (e.g., clinical operations, project and program management, safety and pharmacovigilance, quality, pre-clinical / clinical sciences, manufacturing, finance, contract resources, vendors etc.) in the creation, management, and execution of the clinical development plans, in developing innovative and efficient solutions to medical and scientific clinical trial issues, and ensuring the successful execution and completion of Sierra's clinical trials.
- May also assist with other broad or diverse activities as needed, and when appropriate, including Clinical Development activities (e.g., contributing to the development of an IND for a preclinical asset, etc), Business Development activities (e.g., contributing to Search and Evaluation efforts, Diligence, etc), or other non-clinical departmental activities.
- Regular international travel to attend meetings is required.
- Other related duties as assigned.

Qualifications and Requirements

- Advanced degree such as PhD, Pharm D and 8 year's directly related experience in a clinical development-biopharmaceutical environment, or the equivalent combination of education and experience.
- Demonstrated skills and understanding in clinical trial design and data interpretation.
- Knowledge of applicable FDA Code of Federal Regulations, Good Clinical Practices, and clinical trials guidelines is required.
- A thorough understanding of the phases of clinical development and extensive experience with oncology clinical trials is required.
- Familiarity with the drug approval process through NDA (or BLA) is required; Familiarity with ex-US drug approval process, in addition, is preferred.
- Sufficient content expertise to be able to meaningfully contribute to document development (such as INDs, Protocols, ICFs, IBs, Regulatory packages, etc.) and data review and interpretation under the direction and oversight of the VP, Clinical Development.
- Proven track record of successfully delivering projects on time, to budget and the required quality.
- Excellent interpersonal, verbal and written communication skills (including experience in making presentations).
- Ability to build and maintain effective internal and external professional relationships.
- Leadership and interpersonal skills are a necessity. Must be able to facilitate and work in a team environment.
- In depth understanding of GCP, ICH guidelines and demonstrated experience in Ph 1-3 trial design and execution.
- Excellent communication and interpersonal skills.
- Team player, with the ability to move in a fast paced and dynamic environment.
- Previous supervisory experience preferred.
- Must be able to travel without any legal restrictions across international borders.

How to Apply

To apply for this role, please submit your CV and cover letter in PDF format to hr@sierraoncology.com. Please indicate the position title in the subject line of your email.

We thank you in advance for your interest in Sierra. We will contact you directly should we wish to arrange a meeting to discuss this position further.