Clinical Scientist (Mid-Entry Level)

Description:

In collaboration with a therapeutic area Medical Director or Chief Medical Officer, the Clinical Scientist will contribute to the design, conduct, analysis, and reporting of clinical trials. The Clinical Scientist will apply scientific training and clinical research experience to support all aspects of drug development, from facilitating the transition of molecules from pre-clinical discovery to supporting the registration and commercialization of a product.

Key Responsibilities:

· Contribute to the review, interpretation and communication of scientific data pertaining to the efficacy and safety of compounds in development. Attends congress and reviews literature to develop and augment expertise in therapeutic area

· Help develop program strategy including the clinical development plan, product lifecycle plans, target product profiles and draft labels. Reviews competitive landscape and help identify and evaluate business development opportunities.

· Responsible for providing focused scientific and clinical study support from start-up clinical study report (CSR).

· Participate in scientific education of internal and external stakeholders on the pre-clinical (e.g. mechanism of action, animal models) and clinical (e.g. epidemiology, diagnosis, treatment) data relevant to program. Engage opinion leader interactions to build pipeline awareness and foster research collaborations.

· Contribute to the scientific content of Study Protocols, Investigator Brochures, Clinical Study Reports, Informed Consent Forms, briefing documents, charters, and regulatory documents.

· Contribute to creation of electronic database, IRT, and associated training documents and review data completeness and fidelity throughout study conduct.

· Collaborate cross-functionally to help create a scientific platform in support of the regulatory, commercial and medical education strategy for late-stage assets.

· Ensure adherence to Good Clinical Practices, pharmacovigilance standards, standard operating procedures and to all other quality standards in conducting research. Contributes to authorship of regulatory responses and may participate in meetings.

Qualifications

· Advanced degree (e.g.,Pharm. D, M. D, Phd, MS) preferred, medical related preferred.

Able to provide input and direction to clinical research with appropriate supervision

· Strong desire to collaborate in a cross-functional setting.

· Clinical trial experience in the pharmaceutical industry, academia, or equivalent is preferred.

· Knowledge of clinical trial methodology, regulatory and compliance requirements governing clinical trials and experience in the design of study protocols