Emerald Health Pharmaceuticals
Clinical Operations Associate
Position Description

About the Company

The Emerald Health Pharmaceuticals Inc. (EHP) vision is to make a significant positive difference in the lives of patients through the development of safe, novel medicines in a wide range of therapeutic indications. Our strategy is the development of novel, patented synthetic drugs based on cannabinoid sciencethat affect validated targets for many diseases with unmet medical needs. EHP, a clinical-stage company entering Phase II international studies in autoimmune and fibrotic diseases, is headquartered in San Diego, CA.

EHP was founded in 2017. Since then, we have advanced our lead molecule into Phase II clinical studies for the treatment of multiple sclerosis and systemic sclerosis (a form of scleroderma). Our second development program with another NCE is in preclinical development and is targeting Parkinson's disease and Huntington's disease.

EHP works closely with Emerald Health Pharmaceuticals España to build on our world-leading position in the field of cannabinoid science and pharmaceutical development.

About the Role

The Clinical Project Associate supports the EHP Director of Clinical Operations and EHP Director of Clinical Science with clinical project duties related to ongoing clinical research. The Clinical Project Associate will be responsible for providing support for all stages of clinical research programs by assisting in preparation and maintenance of project specific documents, data listings, procedures, and initiatives to manage the scope, timelines, and budget of clinical development projects. This is a San Diego, CA based position.

Essential Functions

- Supports the clinical team in the planning, execution, and management of operational aspects of clinical programs.
- Tracks and prepares visual presentation of study-specific information utilizing databases, spreadsheets, and other tools.
- Provides updates of study status to Clinical Management on a regular basis with clinical trial metrics.
- Supports data management activities and deliverables.
- Liaises with the Program Management on project schedule.
- Liaises with Corporate Finance on budget forecast and tracking of invoices and actual spending.

- In collaboration with the project team, may contribute to internal and external project materials associated with the clinical development of a product (e.g., protocol, ICF, CRFs, IB, study plans, Study Master File, Clinical Study Agreements, Regulatory submissions).
- Provide support for all stages of clinical research trials by preparing, filing, and maintaining study documentation from investigational sites and/or CROs.
- Assisting in securing necessary supplies for clinical sites.
- Assisting in maintenance of project specific regulatory documents.
- Supports the clinical team in the preparation of and distribution of regulatory documents and other associated study-startup activities including contracts.
- Assists in the development and coordination of project team meeting agendas and minutes.
- Provide quality overview and consistency checks on informed consent forms (ICFs).
- Support the clinical team in TMF inspection readiness and ensures completeness of the TMF for compliance to Good Clinical Practice.
- Supports a continuous state of audit readiness in all aspects of the job.
- Uploads and maintains study documents on study portals.
- Creates and maintains databases related to clinical studies and projects as assigned.
- Participate in project related meetings as needed; take detailed notes at meetings on decisions and action items and distribute the list to the team as needed.
- Supports preparation of clinical regulatory documents, correspondence, tracking, filing, and clinical SOPs.
- Other projects and duties as assigned.

Position Qualifications

Competency Statement(s)

- Detailed oriented with excellent oral and written communication skills in English.
- Must interact positively with co-workers and management and fit with the EHP multinational culture.
- Knowledge of scientific methods, GCPs and regulations relating to clinical research.
- Must have a working knowledge of computer technology and its application to the clinical environment.
- Ability to read, analyze, and interpret project information related to scope, schedule, and budget.
- Must be able to work within time constraints and to think and respond quickly.
- Must possess reasoning and problem-solving skills.
- Ability to work individually with minimal supervision, as well as be a part of a multidisciplinary team.
- Enthusiasm to work in a fast-paced environment.
- Occasional traveling may be required.

Skills & Abilities

Education:

A 2 or 4-year degree with at least 2 years of clinical research related experience in a pharmaceutical company, clinical research organization (CRO) or equivalent.
Computer Skills: Knowledge of MS Word, MS PowerPoint and proficiency in MS Excel and SharePoint. Prior Clinical Data management, contracting and/or accounting experience is a plus.