

**Company:**

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a cutting-edge biotech company focused on the discovery and development of novel therapies for the treatment and prevention of diseases. Capricor's lead product candidate, allogeneic Cardiosphere-Derived Cells (CDCs), known as CAP-1002, is being investigated as a treatment for Duchenne muscular dystrophy (DMC). In addition, the Company is conducting research and development on its exosomes platform technology for inflammatory indications. In response to fight against a global pandemic, our team is applying its cell and exosome technologies against COVID-19, including the development of a potential vaccine.

Capricor offers exciting opportunities to join our expanding team. Capricor provides competitive compensation and benefits packages.

Position:

Senior Clinical Trials Manager

Description:

Under the guidance of the Director of Clinical Operations, the Senior Clinical Trials Manager (SCTM) will have primary responsibility for the planning and managing clinical operations activities. This position is responsible for the conduct and management of single/multiple Capricor-sponsored clinical studies including, but not limited to timeline management, project planning, study communication and management of key project vendors. Strong communication and planning skills are essential to efficiently support the management of operational aspects of the clinical studies. The SCTM will ensure trials are conducted in compliance with ICH/GCP, FDA regulations, health authority guidance, and company SOPs.

Responsibilities:

- Responsible for the project management of a clinical program including the planning, preparation and management of study timelines, budgets, risk, and contingency planning
- Optimizes and leverages processes, tools, metrics, resources and systems to enable effective, efficient and compliant team performance and deliverables
- Assist in the assessment and selection of CROs and other clinical research contracted vendors
- Actively manage CROs and vendors through the course the studies
- Oversees the organization of CRO Kick-off meetings and Investigator's Meetings
- Facilitates strategic decisions and provides leadership direction within the clinical operations function to optimize management of scope, financials and schedule as it impacts project execution
- Manages committees such as DSMBs, CECs, Steering Committees, etc., if needed
- Authors and/or reviews study documents such as study protocols, informed consent templates, monitoring plans, DSMB/CEC/Steering committee charters, Investigator's Brochures, and Clinical Study Reports for Capricor-sponsored clinical trials, if needed
- Leads cross-functional project meetings
- Leads the selection process and qualification of principal investigators for clinical studies
- Responsible for quality management of a clinical program



- In cooperation with other functional groups coaches, develops and trains junior staff on increasing responsibilities and core competencies
- Participates in the development process of internal SOPs, as required

Requirements:

- Scientific background with a minimum of a BS degree; advanced degree preferred
- A minimum of seven years of clinical research experience; 4-5 years as a clinical trial manager
- In-depth knowledge in clinical study design and experience in all aspects of conducting clinical trials and phases of research
- Solid knowledge of ICH/GCP guidelines and regulatory requirements for all clinical development phases
- Strong knowledge of therapeutic area and acute care/hospital trial settings preferred
- Demonstrates strong leadership and management skills with willingness to be heavily involved in the conduct of clinical trials
- Demonstrates internal and external expectation management and alignment
- Strong sense of urgency and commitment to excellence in the successful achievement of defined project objectives
- Ability to prioritize workload to meet multiple project timelines
- Excellent planning and organization skills
- Excellent problem-solving abilities
- Ability to function independently and exercise judgment and decision-making skills
- Ability to travel up to 20%

Applicants should submit a cover letter and their CV to careers@capricor.com