Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a Los Angeles, California based cutting-edge biotech company focused on the discovery and development of novel cell and exosome-based therapeutics for the treatment and prevention of a variety of diseases and disorders. Capricor's lead product candidate, allogeneic Cardiosphere-Derived Cells (CDCs), known as CAP-1002, is being investigated as a treatment for Duchenne muscular dystrophy and COVID-19. In addition, the Company is conducting research and development on its exosomes platform technology for a variety of indications. In response to a global pandemic, our team is currently applying its technologies to deploy a novel vaccination approach against COVID-19. Capricor offers exciting opportunities and invites qualified professionals to join our expanding team. Capricor provides competitive compensation and benefits packages.

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Position:

Senior Clinical Trials Associate

Description:

The Senior CRA will be responsible for the oversight of study monitoring (feasibility, site selection, study start-up, enrollment, conduct and close-out). The Senior CRA will ensure monitoring consistency for all clinical development programs, including consistent study execution through the development of supporting study documents, such as monitoring plans, case report forms and site audit plans, as well as input into other study documents (eg, data management plans). CRAs serve as the primary point of connect between Capricor and investigative site personnel. Other responsibilities include, but are not limited to, the following:

- Participate and coordinate with the clinical team for study set-up, and track day to day project follow-ups.
- Generate trip reports and study related reports.
- Prepare, review and process Serious Adverse Event (SAE) reports.
- Consult and resolve protocol related questions with the Project Manager (PM) and patient related issues with the designated Medical Monitor (MM). Maintain a record of site contacts with the PM or MM concerning protocol deviations and clarifications for the respective sites.
- Review draft protocols and synopses for completeness and feasibility.
- Participate in team meetings and improve communication channels.
- Participate in project status calls and presentations along with the team.
- Conduct regular reviews of site communication, monitoring visit reports, data flow information and audit findings.
- Coordinate and execute preparation of relevant SOPs/Work Instructions and other relevant documents required for projects, audits and business development.
- Develop clinical plans and guidelines, including clinical monitoring plans and assure implementation and adherence.

- Ensure that clinical research studies are conducted in accordance with the protocol, SOPs, ICH-GCP, and applicable local regulatory requirements.
- Coordinate with sites and study team for obtaining study updates, scheduling visits, IRB submissions and generation of reports.
- Participate in study specific training and corporate training programs.
- Impart relevant training to site team members where required.
- Actively participate in the preparation and coordination of investigator meetings and attend when required.
- Develop patient enrolment strategies with the project team and study sites.
- Ensure proper storage, dispensation, and accountability of all Investigational Product(s) and trial-related materials.
- Prepare for sponsor or internal audit program undertaken in the organization.
- Report timesheets regularly.
- Maintain training records for self and relevant team members.
- Generate and review Minutes of Meeting (MoM) for internal team meetings, client meetings and teleconferences, as and when necessary.
- Ensure that the project timelines are met.

Required Educational Background and Skills:

- Bachelor's Degree and/or equivalent with at least 7-10 years experience of conducting onsite and remote monitoring in the biopharmaceutical industry.
- Working knowledge of FDA regulations, DIA Reference Model and ICH guidelines regarding GCPs.

Knowledge, Skills and Attributes:

- Strong interpersonal skills as well as ability to adapt to function in a team environment.
- Proven ability to multi-task and prioritize.
- Well-organized, detail-oriented, possess a sense of urgency.
- Team-oriented with very good communication and interpersonal skills.
- Excellent computer skills in the following programs: Microsoft Outlook, Word, PowerPoint and Excel.

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