Clinical Trial Assistant

Capricor, Inc. (NASDAQ: CAPR) is a clinical-stage biotechnology company focused on the discovery, development and commercialization of first-in-class biological therapeutics for the treatment of rare disorders. Capricor's lead candidate, CAP-1002, is an allogeneic cell therapy that is currently in clinical development for the treatment of Duchenne muscular dystrophy. Capricor has also established itself as one of the leading companies investigating the field of extracellular vesicles, or exosomes, and is exploring the potential of CAP-2003, a cell-free, exosome-based candidate, to treat a variety of disorders. For more information, visit www.capricor.com.

Capricor recently opened up a new Clinical Operations office in San Diego and has an opening for a Clinical Trial Assistant.

Responsibilities:

The Clinical Trial Assistant supports the efforts of Clinical Operations and performs a variety of administrative assignments such as in-house management of essential documents, study tracking tools and metrics, and the set up/maintenance of the Trial Master Files.

Study-Specific Activities:

- Establishes, performs quality control, maintains, and archives the Trial Master File (i.e., electronic folder set-up, filing, tracking, archiving) in compliance with DIA Reference Model, SOPs, ICH and GCPs. Ensures proper naming conventions are followed.
- Coordinates distribution of documents and equipment/materials to sites as well as monitors, central/core laboratories and CROs.
- Collects, tracks and reviews regulatory documents and notifies sites, monitors or CRO of missing or expired documents.
- Develops and maintains spreadsheets and other documents to track critical study milestones.
- Tracks and reports on project or study information regarding subject and site status, metrics, lab sample shipments and discrepancies, and other parameters as appropriate.
- Responsible for preparing, collecting, tracking and reviewing all Annual Follow-up documents.
- Prepares or assists with the preparation and review of study-related materials as it pertains to CTA processes (e.g., study reference manual, clinical trial material requests, and Investigator Site File).
- Participates in team review of data listings and clinical study reports. Submits required documentation for appendices of clinical study reports or for inclusion into a regulatory filing.
- Organizes study information on the shared file drives and retrieves information from the central/core laboratories or CRO portals.
- Assists Clinical Trial Managers with oversight of third-party vendors and other clinical operations tasks.

Communication and Coordination:

- Performs assigned administrative activities in support of clinical trials from design to completion.
- Participates in the planning and conduct of central/core laboratory, CRO and study-related meetings; creates agendas and draft minutes as appropriate.
- Sets up and attends meetings, takes meeting notes, and updates and distributes meeting minutes.
- Organizes and helps plan meetings. May interact with meeting planners and travel agents.
- Communicates to internal and external team members (e.g., vendors, site personnel, and consultants).
- Coordinates the distribution of communications to all sites (e.g., questionnaires, newsletters, mass mailings, IND safety reports, Investigator's Brochures, etc.).

Other Departmental Activities:

- Assists the Clinical Finance Manager with tracking and processing of vendor or site invoices and ensures accurate accrual records are kept.
- Maintains up-to-date knowledge of current regulations and guidelines to ensure compliance.
- Provides general administrative support to the clinical team as assigned.
- Processes forms, requests for information by the team, and requests to obtain information from vendors and investigative sites.
- Performs other duties as assigned.

Preferred educational background and skills required:

- Bachelor's Degree and/or equivalent with at least 2 years of CTA experience in the biopharmaceutical industry.
- Past experience in development of tools and other tracking documents that support clinical research.
- Working knowledge of FDA regulations, DIA Reference Model and ICH guidelines regarding GCPs.

Knowledge, Skills and Attributes:

- Proven ability to multi-task and prioritize.
- Well-organized and detail-oriented; possesses a sense of urgency.
- Team-oriented with very good communication and interpersonal skills.
- Excellent computer skills in the following programs: MS Outlook, MS Word, PowerPoint and Excel.

Special Considerations:

Some travel may be required to sites or to study-related meeting.

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

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