Positions (Minimum 3+)

- Clinical development
- Project manager

The clinical operations team is responsible for the execution of all Phase 1-3 clinical trials, across all therapeutic areas. Working with other departments/functions, clinical operations ensures that all clinical trial activities are performed in accordance with regulatory guidelines to provide timely delivery of high-quality clinical data to support the registration and commercialization of the products.

Locations: Pangyo, Korea or Orinda, CA, USA

Job Descriptions

- Manages global Phases I-III outsourced studies.
- Drafts and coordinates review of relevant documents including protocols, informed consents, case report forms, monitoring plans, investigator brochures, and clinical study reports.
- Manages study timelines.
- Contributes to development of study budget.
- Contributes to development of RFPs and participate in selection of CROs/vendors.
- Manages CROs/vendors.
- Coordinates review of data listings and preparation of interim/final clinical study reports.
- Ensures effectiveness of site budget/contract process.
- May be asked to train CROs, vendors, investigators, and study coordinators on study requirements.
- Conducts oversight monitoring visits of CRO or study sites as required.
- Interacts with cross-functional teams internally and externally to ensure trial progress.

Clinical Trial Project General Manager or Director
Qualifications:

- Knowledge of the drug development process with 6 plus years and a Ph.D. in a scientific field or a PharmD, DVM, or MD degree.

- A minimum of 5 years of Clinical Project Management and/or Clinical Operations experience at a Sponsor or CRO, preferably in hematology/oncology or a MS or MBA.
- Experience should include 5 years of participation in cross functional project management in various stages of development.
- Project Management Certification: PMP or equivalent is desirable, with working knowledge of associated methodologies and principles.
- Solid understanding of applicable clinical research and scientific concepts and regulatory requirements.
- Excellent communication skills both verbal and written are required; Fluent in English and Korean, preferred.
- Strong problem-solving skills with the ability to focus on time-sensitive objectives and proven flexibility adapting to a rapidly evolving workload.
- Excellent IT skills, particularly MS Office Excel, Word, Project and ability to track costs/budgets/financial reporting relating to project execution.
- Able to communicate and work with cross functional team, internally and externally.

Clinical Trial Project Management Position
Preferred experience, knowledge and skills:

- Educated to degree level or above within a scientific discipline. (Ph.D. preferred)
- Oncology experience is highly desired.
- Must have clinical trials experience including study management/coordination.
- Monitoring experience highly desirable as site oversight monitoring visits will be required.
- Thorough knowledge and understanding of FDA and EU Regulations, ICH Guidelines, and GCPs governing the conduct of clinical trials is desirable.
- Must be able to generally understand, interpret, and explain protocol requirements to others.
- Ability to participate in multiple departmental or interdepartmental strategic initiatives under limited supervision.
- Must have a general, functional expertise to support SOP development and implementation.
- Self-motivated, assertive and able to function independently or as part of a team.
- Effective in selection of investigative sites, CROs, and vendors and management of external resources.
- Strong interpersonal and negotiation skills as well as strong verbal and written communication (including presentation of materials to internal teams and external partners).
- Proven problem solving and decision-making skills and must be able to work under minimal and at times no supervision, determine personal work plan, and schedule tasks and activities.
- Ability and willingness to travel 10-20% (domestic and international).