HENGRUI THERAPEUTICS, INC.
506 Carnegie Center, Suite 102, Princeton, NJ 08540

Senior Manager, Clinical Project Management

Hengrui Therapeutics, Inc. (HTI) is recruiting for a Senior Manager, Clinical Project Management, located in Princeton, NJ.

HTI is a biotechnology startup, focusing on early stage clinical development of innovative therapeutic solutions in areas of major unmet medical needs, such as oncology, dermatology, cardiovascular/metabolic disorders, immunology and neuroscience. We offer abundant opportunities for motivated pharmaceutical professionals to pursue their scientific/clinical interests, make an impact and maximize their growth potential.

Job Description

The Senior Manager, Clinical Project Management (referred to herein as "Project Manager") will provide support to HTI's clinical development operations, trial execution strategy and project management. This individual will facilitate the cross functional preparation, implementation and facilitation of projects related to HTI's clinical trials in the US and globally as assigned.

The Project Manager will also support various project activities, including but not limited to: clinical project initiation, budgeting, planning, execution and completion, which may include managing clinical project timelines, budgets and deliverables; process development; study tracking; providing status updates; project communication; information/data gathering and reporting; coordinating and facilitating meetings; tracking, escalating and resolving issues; tracking and mitigating risks; contingency planning and managing resources. The Project Manager will plan and manage projects or sub-projects with or without a CRO.

Essential Functions

- Responsible for leading US and/or global cross functional project teams in the planning and delivery of all clinical studies within a program, in accordance with the scope, quality,

budget and timeline requirements, and managing resources and risks in compliance with SOPs, applicable global regulations and ICH/GCP guidelines.

- Chair team meetings for assigned projects ensuring goals and deliverables are clearly defined, and issues, decisions, risks and action items are appropriately tracked.
- Provide leadership, guidance, global clinical trial expertise and direction to internal and external project teams to ensure process consistency and knowledge sharing.
- Develop project level budgets and timelines based on project and global business needs.
- Manage vendors/CROs and functional contractors. Lead vendor selection for assigned projects. Oversee vendor management for assigned projects, including negotiation of scope of work, budgets, performance management and issue resolution.
- Assess current and projected demands of a clinical study or program, and partner with department head and leadership to identify and secure resources.
- Analyze and develop action plans for investigational site, vendor and administrative issues.
- In collaboration with the Medical Director, analyze, develop action plans and escalate safety issues, patient care issues, and study design and/or conduct issues.
- Plan, prepare and present at investigator meetings.
- Oversee and contribute to development of key study documents including, but not limited to study protocols, protocol amendments, study plans and procedure manuals, project tools, informed consent forms and clinical study reports. Contribute to development of the compound/project clinical development plan.
- Evaluate, manage and facilitate the timely flow of clinical data to support project objectives.
- Oversee forecasts to maintain sufficient clinical and non-clinical supplies.
- Prepare and present study or project specific updates.
- Represent Project Management & Clinical Operations in partnered development programs.
- Participate in or lead process development initiatives, as required.
- Other duties as assigned.

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Required Qualifications

- Bachelor's Degree (scientific or medical discipline preferred). Graduate degree is a plus.
- A minimum of at least 9 years of relevant pharmaceutical development experience including at least 5 years of clinical project management in the pharmaceutical industry
- Applied knowledge of FDA regulations and ICH GCP guidelines
- Ability to manage projects and lead study team(s) with minimum supervision, deal with ambiguity, multitask and maintain tight timelines and priorities in a highly professional manner
- Experience in vendor oversight and managing contractors to deliver desired outcomes
- Fluent in MS Project, Excel, PowerPoint and Word tools
- Demonstrated ability to lead a team and to be an adaptable and solution oriented team player
- Experience working with multi-disciplinary cross-cultural teams in a matrix environment
- Experience developing study and program execution strategies and risk mitigation

Preferred Qualifications

- Experience working in large and small company settings
- Certificate or training in Project Management a plus

Travel Estimate: up to 10%

Primary Location North America-United States-Princeton, NJ

Organization Hengrui Therapeutics, Inc.

Job Function Clinical Operations/Project Management

***Please include salary requirements when submitting CV/Resume to: info@hengruitherapeutics.com**