



Sr. Clinical Project Manager

Company overview

NextCure is a growing clinical-stage biopharmaceutical company located in Beltsville focused on discovering and developing first-in-class immunomedicines for the treatment of cancer and other diseases. NextCure is committed to professional development in the context of learning, managing, and developing its employees. We create a unique environment for our employees, providing exposure to various facets of our operations cultivating career growth and development. We are excited about the ongoing work at NextCure and invite you to come join us in the culture and build your career in an environment that nurtures professional growth and development.

Role Summary

We are seeking a highly motivated Sr. Clinical Project Manager to support NextCure Data Management for the successful delivery of our product pipeline. The Sr. Clinical Project Manager will be responsible for all activities related to implementation of clinical studies including the execution of the clinical trial end to end, development of protocols, building database, and ensuring that clinical trials are conducted in a timely fashion and compliant. The candidate must thrive and adapt to a fast-paced, innovative and changing environment.

Responsibilities

- Act as project manager on one or more projects
- Development and maintenance of the assigned project management plan and study manual(s)
- Plan, conduct, and manage research projects within the relevant regulations and policies
- Maintain assigned project regulatory documents as per NextCure guidelines and SOPs
- Align internal business needs and expectations with external CRO partners
- Facilitate communications with CROs and Vendors to ensure satisfaction
- Assist in preparation of project invoices
- Ensure site management follows the study plans
- Track all aspects of the research project and make regular progress reports
- Maintain regular communications with the study teams
- Identify issues and challenges and work with NextCure Director(s) to resolve any matters
- Participate in regular activities of Clinical Operations Team
- Plan and execute planning, procurement, assessments, and implementations
- Ensure regulations are being implemented according to ICH\GCP, SOPs
- Manage projects process and procedures to meet set timelines



Required education and experience:

- Master's in Science, Clinical Research Administration, or related field
- Minimum of 5 years prior relevant experience in the industry or relevant clinical research organization
- Prior project management/clinical operations experience
- Excellent working knowledge of FDA & ICH/GCP regulations and guidelines
- Experience building clinical operations groups and associated infrastructure
- Ability to travel 10% (after Covid)

Qualifications:

- Good understanding of the drug development process
- Experience/understanding of the overall Clinical Trial process
- Good understanding of potential risks around clinical trial data collection
- Experience creating process flows, build process maps, conduct gap analysis, and outline process optimization
- Project management skills including expertise in metrics analysis and reporting methodologies
- Strong experience with MS Project, Excel (pivot tables, graphing) and PowerPoint
- Experience in handling multiple special projects along different touch points of the clinical lifecycle

NextCure is an Equal Opportunity Employer and offers a competitive salary and benefits package in a scientifically engaged team work environment.

Qualified candidates should email their resume to info@nextcure.com.