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syros.com

Senior Clinical Trial Manager

Syros Pharmaceuticals is pioneering the understanding of the non-coding region of the genome to advance a new wave of medicines that control expression of disease-driving genes. Syros has built a proprietary platform to systematically and efficiently analyze this unexploited region of DNA in human disease tissue to identify and drug novel targets linked to genomically defined patient populations. Because gene expression is fundamental to the function of all cells, the Company's gene control platform has broad potential to achieve profound and durable benefit across a range of diseases. Syros is focused on cancer and immune-mediated diseases and is advancing a growing pipeline, including its lead drug candidates SY-1425, a selective RARα agonist for genomically defined subsets of patients identified by its platform, for a range of cancers including acute myeloid leukemia and myelodysplastic syndrome, and SY-1365, a selective CDK7 inhibitor for a range of blood cancers and solid tumors. Led by a team with deep experience in drug discovery, development and commercialization, Syros is located in Cambridge, Massachusetts.

Key Responsibilities

Reporting to the Vice President of Clinical Operations, this is a high-impact position in a small clinical operations department with substantial growth opportunities. The successful candidate will be responsible for:

- Coordinating interdisciplinary activities, leading study and/or clinical teams, and collaborating with the development team to formulate clinical development strategies, set goals and establish timelines
- Contributing to the clinical development strategy/plan, working with an integrated drug development team, and various clinical sub-teams
- Contributing to the development of the clinical study protocol, and related documents including the informed consent. Includes authoring initial and amended protocols, consents, eCRFs, and ancillary documents to support the study
- Supporting the development of clinical sections of various regulatory documents: clinical study reports, investigator brochures, annual reports, safety data reviews and safety update reports
- Liaise with clinical sites as appropriate to ensure optimal Sponsor-site relationships
- Contribute in the development and review of data management related activities
- Identifying study and program issues by reviewing and monitoring emerging clinical safety and efficacy data and developing strategic solutions to identified issues
- Evaluation, selection and management of Contract Research Organizations (CROs) and other external vendors to ensure successful clinical trial implementation
- Provide input to the development program budget(s) and accountable for managing overall clinical study budget(s)
- Work directly with CROs, vendors, investigators, monitors, KOLs and other external partners as needed
- Contribute in the development/participation/coordination of Investigator Meetings, Study Initiation Visits
- Review and contribute to development of department standard operating procedures
- Review and present clinical trial data, prepare presentation material as needed for internal and external meetings
- Manage all aspects of study progress from planning to close-out to assure adherence to intended timelines and achievement of study goals while ensuring quality in accordance with FDA, EMEA, GCP, and ICH guidelines

Success Factors

- Strong technical project management skills and clinical operations knowledge

- Possesses a sense of urgency and an ability to anticipate and respond quickly to emerging information
- Confident and self-motivated with the ability to act with clarity in urgent situations Entrepreneurial and passionate; enjoys working in a fast-paced, small-company environment
- Excellent oral and written communication skills for effectively interfacing with vendors, sites, and internal stakeholders
- Strong leadership, interpersonal, organizational and multi-tasking skills
- Willingness to work collaboratively to develop and execute on project plans
- Proactively seeks out, recommends and executes process improvements
- Resourceful, creative, enthusiastic, and results-oriented
- Excellent attention to detail and problem solving skills
- Acts with integrity and respect at all times

Job Requirements

- BS/MS degree
- Experience 4+ years clinical research in industry, including a minimum of 1 year as a clinical trial manager
- Oncology clinical trial experience preferred
- Science background preferred
- Strong knowledge and understanding of GCP/ICH Guidelines for conducting clinical trials (Phases 1-3)
- Demonstrated knowledge of clinical trial management including study start-up, clinical monitoring, patient recruitment, clinical trial data oversight and data deliverables, risk management, timeline management, and study budget management
- Travel as needed

Finally, the candidate will need to embrace our values:

As a team we:

• are committed to transform the lives of patients
• are pioneering in our science
• challenge each other to achieve excellence
• work with passion, integrity and respect
• like rigorous work and serious fun