Senior Director Clinical Operations Program Lead

Hiring organization
Dyne Therapeutics

Job Location
Waltham, Massachusetts, United States

Base Salary
$ 100000 - $ 155000

Date posted
May 17, 2024

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Description

Role Summary: The Clinical Operations (Program) Lead is the clinical operations functional representative for the Program Team, is responsible for developing and leading the strategy, planning, oversight, implementation and delivery of program and study level clinical operations deliverables as outlined in the clinical development plan (CDP). This individual is responsible for providing advanced functional and technical expertise and insights from both a strategic (decision points, risk) and operational (timeline scenarios, feasibility & financials) perspective to meaningfully contribute and make recommendations to the integrated development plan (IDP) and other key plans, such as the CDP, necessary to advance Dyneâ??s clinical programs. This individual develops and oversees implementation of program clinical operational strategy, ensuring appropriate considerations that include but are not limited to technical, vendor, quality site/ Investigator, geographical and patient centric considerations for the Programâ??s lifecycle. This individual may be responsible for one highly complex or multiple medium complexity clinical programs. This individual may have one or more direct reports. This role is expected to require up to 20% travel, including international travel. This role is based in Waltham, MA without the possibility of being remote. Primary Responsibilities Include: Leads the development and ongoing refinement of Program level study timelines and scenarios in order to contribute to the CDP, IDP and other high-level strategic plans Provide rigorous, objective information (operational status and updates) to the Program team and, as necessary, Dyne senior leadership to help support strategic project decisions. Takes overall accountability for operational delivery of the clinical studies within a Program and provide appropriate oversight to ensure a high quality, ethical, cost efficient way to meet timelines and patient recruitment goals. Actively participates in Program team and other applicable sub-team meetings, collaborating and integrating with other functions within research and development, medical, and commercial in order to deliver on the CDP/IDP. Responsible for the development and execution of a Program strategic clinical operations plan, taking into account the therapeutic area and underlying science and opportunities for innovation and operational consistency as well as the future clinical, regulatory, and commercial development plan for the molecule. Proactively integrates stage-appropriate needs into the operational strategy. Oversees, mentors and works collaboratively with Clinical Study Lead(s) and other clinical operations and supportive roles within the Program (clinical trial managers or associates, quality representative, vendor managers, etc.) Overall accountability overseeing and driving CRO and other vendor relationships to ensure execution of clinical studies within the Program, within timelines, budget and with quality Participates in departmental and cross functional risk assessment, technology development and process improvement initiatives, including SOP development, review and maintenance. Participate/lead in site engagement programs to help build relationships with key opinion leaders, investigators, and clinical site staff to support the clinical study activities and delivery Engage with patient advocacy groups to help build patient-focused clinical operations strategies, methods and tools for use in the clinical studies Create and implement risk assessment and mitigation plans, performing regular reviews to continually assess for changes Attend seminars, congresses, advocacy meetings, Investigator meetings, Program and sub-team meetings, educational conferences/training sessions Provide management, training, oversight, coaching, mentoring and development to one or more direct reports Education and Skills Requirements: Undergraduate degree in a scientific or health related discipline. Advanced scientific or business degree or equivalent experience desirable. Minimum of 10 years experience in drug development, clinical research and operational strategy

experience including responsibility ensuring studies and programs are executed to quality, timelines and budget (at least part of this time in a Biotech/Pharma environment is preferred) Demonstration of project/program management skills including risk assessment, timeline and budget management and contingency planning Demonstration of effective team leadership of matrix teams. Excellent communication, management and organizational skills, along with problem solving, conflict resolution, and team building skills Experienced in identifying and leveraging relevant data and information to develop well-conceived and executable timelines Experience across several complex therapeutic areas; neuromuscular or muscle disease experience preferred. Experience with rare disease and/or pediatric trials also preferred Scientifically and clinically agile, proven ability to learn and apply relevant disease information into strategic operational planning and delivery Deep operational expertise. Experience planning and delivering global clinical programs and studies Independently motivated, detail oriented and good problem-solving ability (think outside of the box mentality) Experience in participating or facilitating the development of Clinical Development Plans (CDPs) with multiple functions strongly desired Excellent organizational skills, with an ability to embrace change and multi-task in an extremely fast-paced environment Enjoys building relationships with KOLs and site personnel, with a willingness to travel to establish and build relationships Experience with engaging and working with Patient Advocacy groups beneficial Experience with hiring, managing, mentoring and/or developing direct reports preferred Up to 20% travel, including internationally #LI-OnsitePlease mention the word **ENTHRAL** and tag RMjE2LjI0NS4yMjEuOTE= when applying to show you read the job post completely (#RMjE2LjI0NS4yMjEuOTE=). This is a beta feature to avoid spam applicants. Companies can search these words to find applicants that read this and see they’re human.

Contacts
Job listing via RemoteOK.com