Senior Clinical Research Associate (Remote Position)

Job ID
REQ-10039727
März 01, 2025
USA

Summary

This is a Remote Based position. Candidate must be located near an airport (California, Oregon, Washington, Montana & Nevada - highly desirable locations). The successful candidate will be required to travel up to 80% of the time. The Senior CRA performs monitoring activities related to initiation, conduct (recruitment, quality data collection) and timely completion of Phase I-IV Pharma clinical trials within the country.

The Senior CRA is responsible to deliver data within timelines and required quality standard, and adherence to monitoring procedures in accordance with ICH/GCP and US CFR and company SOPs.
LI-#Remote

This position can be based remotely anywhere in the U.S. (there may be some restrictions based on legal entity). Please note that this role would not provide relocation as a result. The expectation of working hours and travel (domestic and/or international) will be defined by the hiring manager. This position will require 80% travel.

About the Role

Your Key Responsibilities:

Trial Monitoring strategy:

• Serves as the primary site manager for assigned clinical investigative sites (first point of contact between investigative site staff and Novartis)

Allocation, initiation and conduct of trials:
• Is the frontline liaison between Novartis and sites to ensure successful collaboration, meeting Novartis expectation on milestone and deliveries
• Manages assigned study sites/networks, conducting phase I-IV protocols according to the monitoring plan and Novartis procedures
• Facilitates the preparation and collection of site and country level documents
• Performs Site Initiation Visit, ensures site personnel are fully trained on all trial related aspects and performs continuous training for amendments and new site personnel as required.

• Conducts continuous monitoring activities (onsite and/or remote). Implements site management activities to ensure compliance with protocol, GCP, global and local regulations, global and local processes to secure data integrity and patient safety.

• Accountable for continuously updating all relevant electronic systems to perform job functions

• Takes on the responsibility as SME (Subject Matter Expert) as needed

Delivery of quality data and compliance to quality standards:

• Monitors studies as per current legislations, ICH/GCP and Novartis standards
• Ensures timely delivery, of high quality, robust and reliable data of the monitored sites to support the goals of Trial Monitoring as defined by Trial Monitoring.

• Identifies, resolves & escalates issues appropriately
• Collaborates with internal stakeholders and site personnel to manage data query resolution process to ensure timely and accurate data entry

• Proactively collaborates with the Clinical Project Manager (CPM) and CRA Manager as well as Medical Scientific Liaison (MSL), Clinical Regional Medical Director (CRMD), medical advisor and Strategic Site Partner to achieve key accountabilities

•Partners with SSU CRA to ensure seamless transition of site responsibility

Role Requirements:

• BS/BA degree. Scientific or healthcare discipline preferred
• Minimum of 3 years' experience in site monitoring strongly preferred

• Oncology monitoring experience

• CAR-T experience is highly desirable
• Excellent knowledge of the drug development process specifically clinical trial/research
• Knowledge of international standards (GCP/ICH, FDA, EMEA)
• Ability to manage multiple priorities and manage time efficiently.

• Excellent Site management capabilities with demonstrated negotiating and problem-solving skills

• Strong communicator and presentation skills (oral and written)

• Fluent in both written and spoken English

Driving is an Essential Function of this Role: Meaning it is fundamental to the purpose of this job and cannot be eliminated. Because driving is an essential function of the role, you must have a fully valid and unrestricted driver's license to be qualified for this role. The company provides reasonable accommodations for otherwise qualified individuals with medical restrictions if an accommodation can be provided without eliminating the essential function of driving.

COVID-19 Vaccine Policy (customer-facing roles only): While Novartis does not require vaccination for COVID-19 or proof of a recent negative test result for COVID-19 at this time, employees working in customer-facing roles must adhere to and comply with customers' (such as hospitals, physician offices, etc.) credentialing guidelines, which may require vaccination. As required by applicable law, Novartis will consider requests for reasonable accommodation for those unable to be vaccinated. This requirement is subject to applicable state and local laws and may not be applicable to employees working in certain jurisdictions. Please send accommodation requests to Eh.occupationalhealth@novartis.com.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of

employment is expected to be between: $103,600 and $192,400/year; however, while salary ranges are effective from 1/1/25 through 12/31/25, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills, and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an “at-will position” and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients’ lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we’ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

Accessibility & Reasonable Accommodations

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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REQ-10039727

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