

Senior Clinical Research Associate

Job ID
REQ-10012691
Jul 02, 2024
USA

Summary

Remote Position This is a Remote Based position and will be covering our Midwest Region. Candidates must be located near an airport hub, St Louis, Chicago, Kansas City, Denver- 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 Oncology and 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.

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
- 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

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>

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Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between \$112,800- \$169,200 annually; however, while salary ranges are effective from 1/1/24 through 12/31/24, 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.

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Division

Development

Business Unit

Innovative Medicines

Location

USA

Site

Field Non-Sales (USA)

Company / Legal Entity

U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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