

Senior Clinical Research Associate

Job ID REQ-10005910 Mai 08, 2024 USA

Zusammenfassung

100,000. That's how many patients participate in our clinical trials at any given time. Global Clinical Operations (GCO) touches patients' lives every day acting as a link between science and medicine. Envision the impact you could have! #GCO

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 for adherence to monitoring procedures in accordance with GCP and ICH, local regulations and SOPs. Major Accountabilities (

- Conducts feasibility and screen potential Investigators and networks to evaluate capabilities for conducting clinical trials
- Conducts site selection for potential sites to evaluate their capabilities for conducting a clinical trial. Recommends sites to participate in clinical trial
- Is the frontline liaison between Novartis and sites to ensure successful collaboration, meeting Novartis expectation on milestone and deliveries
- Manages assigned study sites and networks, if applicable, 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 is fully trained on all trial related aspects. Performs continuous training for amendments and new site personnel as required. Retrains site personnel as appropriate
- Conducts continuous monitoring activities (onsite and 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
- Is accountable for continuously updating all electronic systems (global and local) relevant to perform job functions
- Negotiates investigator remuneration; prepares financial contracts between Novartis and investigational sites
 and investigators. Ensures that payments are appropriately triggered to investigational sites
 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.

About the Role

- Degree in scientific or healthcare subject area.
- 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.
- Basic project management skills to support in CSM activities.

Why Novartis? Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

Commitment to Diversity and Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

US Accessibility and Reasonable Accommodations: Individuals in need of a reasonable accommodation due to a medical condition or disability for any part of the application process, or to perform the essential functions of a position, please send an e-mail to tas.nacomms@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.

Commitment to Diversity & Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

The pay range for this position at commencement of employment is expected to be between \$107,200 and \$160,800 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.

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 who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds and perspectives. 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. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

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 <u>us.reasonableaccommodations@novartis.com</u> 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.

Abteilung

Development

Business Unit

Innovative Medicines

Ort

USA

Website

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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Job ID

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