Senior Clinical Research Associate

Job ID
391369BR

Apr 25, 2024

South Korea

About the Role

Internal Role Title: Senior Clinical Research Associate

Location: Seoul, Korea #LI-Hybrid

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

About the Role:

This role is assigned to more sophisticated trials and or to less experienced sites where applicable. This person takes on the responsibility to participates in audit organization and inspection readiness activities for monitoring and site related activities as required and ensures implementation of corrective actions within specified timelines and participates in multi-disciplinary teams locally and globally to evaluate and implement process improvements.

We are looking for Clinical Research Associate or Senior Clinical Research Associate. You may refer for more details at the essential requirements column.

Key Responsibilities:

- Frontline liaison between Novartis and sites to ensure successful collaboration, meeting Novartis expectation on achievement and results with true ownership attitude. Handles assigned study sites, conducting phase I-IV protocols according to the Monitoring Plan and Novartis procedures.
- 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. Re-trains site personnel as appropriate
- Conducts continuous site monitoring activities (onsite and remote). Implements' site management activities to ensure compliance with protocol, ICH/GCP, global and local regulation including Health Authorities, IRB/EC, data privacy requirements, global and local processes as applicable. Documentation according to GDP and Novartis standards.
- Identifies deficiencies in site processes and supervise site processes performed outside the site, works in close collaboration with site on risks mitigation and process improvements
- Promotes a compliance culture advocating adherence to the highest standards and ethical integrity, ensuring human subject protection and reliability of trial results at all times
- Establish a positive relationship and true collaboration with the site, to increase patient density and decrease issues at site. Early engagement with site on patient inventory and patient flow in advance of SIV in close collaboration with global and local study team
- Performs Site Closeout activities per SOPs and applicable regulations to ensure that site is aware of any follow-up activity and archiving requirements. Attends onboarding-, disease indication and project specific training and general CRA training as required
- Proactively collaborates with the relevant teams to ensure efficient recruitment, site development and data quality.
- Ensures that relevant site insights are shared with internal partners such as site partnership manager, medical advisor, MSL and CRMA etc. to improve one Novartis approach to sites. Participates in audit organization and inspection readiness activities for monitoring and site related activities as required and ensures implementation of corrective actions within specified timelines.
- Collaborates with internal partners and site personnel to handle data query resolution process and to ensure timely and accurate data entry. Responsible for collecting crucial documents from site and accountable to keep sTMF(s) up to date.

Diversity & Inclusion / EEO

We are committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

Role Requirements

Essential Requirements:

- 2-3 years' experience in global SIT experience as a CRA and for Senior CRA position,at least 4

years of Global SIT experience. Degree or equivalent experience in scientific or healthcare subject area
- Proficient in both written and spoken English and country language. Decision capability
- Excellent time management and organization capabilities, including ability to prioritize and multi-task. Knowledge of international standard and understanding the purpose of the CRA
- Good knowledge of drug development process specifically in clinical trial or search, clinical and therapeutic knowledge
- Ability to travel domestically (and possibly internationally) as needed to study sites and for training and meetings.
- Good communications skills, relationship management, ability to handles site independently, good analytical thinking and ability to anticipate potential issues and take appropriate action.
- Digital and tech capabilities.

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

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

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

Division
Development

Business Unit
GCO GDD

Location
South Korea

Site
Seoul

Company / Legal Entity
NOV KOR

Functional Area
Research & Development

Job Type
Full Time

Employment Type
Regular

Shift Work
No

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Job ID
391369BR

Senior Clinical Research Associate

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