

Senior Clinical Research Associate - Poland (home-office)

Job ID
REQ-10022104
Sep 27, 2024
Poland

Summary

Site relationship management role to ensure sustainable trial execution at Site. Performs on-site and remote monitoring activities related to initiation, conduct and timely completion of Phase I-IV GDD trials within the country in adherence with monitoring procedures and processes in accordance with ICH/GCP, local regulations and SOPs. Proactive site performance management (recruitment & quality) and early identification of real site needs and issues as the single best point of contact (internally & externally) for all sites (from issue management to risk identification).

Senior Clinical Research Associate (sCRA) is assigned to more complex trials and/or to less experienced sites where applicable. Associate takes on the responsibility as SME (Subject Matter Expert) as needed, 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.

About the Role

Major accountabilities:

- Frontline liaison between Novartis and sites to ensure successful collaboration, meeting Novartis expectation on milestone and deliverables with true ownership mindset
- Manages 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 monitor 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 highest standards and ethical integrity, ensuring human subject protection and reliability of trial results at all times
- Establish a strong partnership 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 SSO Clinical Project Manager (CPM) and CRA Manager as well as MSL, CRMA and medical advisor to ensure optimal recruitment, site development and data quality
- Ensures that relevant site insights are shared with internal stakeholders 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 stakeholders and site personnel to manage data query resolution process and to ensure timely and accurate data entry
- Ensures the site Investigator Folder is up to date. Responsible for collecting essential documents from site and accountable to keep sTMF(s) up to date

Minimum Requirements:

- Degree in scientific or healthcare discipline
- Fluent in both written and spoken English and Polish
- Minimum 3 years pharmaceutical industry experience or other relevant experience
- 1+ years field monitoring experience is must
- Risk-based monitoring experience is desirable
- Excellent time management and organization capabilities, including ability to prioritize and multi-task
- Risk based mindset
- Good knowledge of drug development process specifically clinical trial/research
- Clinical and therapeutic knowledge
- Knowledge of international standards (GCP/ICH, FDA,EMA)
- Fast change adaptability to best partner & influencing with sites on fast changing landscape
- A minimum of 50% overnight travel may be required
- Good communication skills, ability to influence others & Relationship management
- Excellent communicator and presenter (oral and written)
- Ability to manage sites independently; Proven ability to work independently with minimal supervision
- Good analytical thinking
- Digital & 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/people-and-culture>

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>

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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<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>

Division

Development

Business Unit

Innovative Medicines

Location

Poland

Site

Warsaw

Company / Legal Entity

PL03 (FCRS = PL003) Novartis Poland Sp. z o.o.

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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