Senior Clinical Research Associate - Poland (home-office)

Job ID
REQ-10058783

8月 01, 2025

Poland

摘要

About the role:

In this role you will be responsible for the Site relationship management and ensure sustainable trial execution at Site. You perform on-site and remote monitoring activities related to initiation, conduct and timely completion of Phase I-IV Global Drug Delivery (GDD) trials within the country in adherence with monitoring procedures and processes in accordance with ICH/GCP, local regulations and SOPs.

You will proactively manage the site performance (recruitment & quality) and ensure 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).

As Senior Clinical Research Associate (sCRA) you will be assigned to more complex trials and/or to less experienced sites where applicable. As needed, you will take on the responsibility as SME (Subject Matter Expert), participate in audit organization and inspection readiness activities for monitoring and site related activities, ensure implementation of corrective actions within specified timelines and participate in multi-disciplinary teams locally and globally to evaluate and implement

process improvements.

This is a field force position (home office based) and requires frequent travelling within country (a minimum of 50% travel with overnight stay may be needed).

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
- **Management of assigned study sites,** conducting phase I-IV protocols according to the Monitoring Plan and Novartis procedures
- **Performing 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
- **Conducting 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.
- **Identifying deficiencies** in site processes and monitor site processes performed outside the site, works in close collaboration with site on risks mitigation and process improvements
- **Promoting a compliance culture** advocating adherence to highest standards and ethical integrity, ensuring human subject protection and reliability of trial results at all times
- **Establishing 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
- **Performing Site Closeout activities** per SOPs and applicable regulations to ensure that site is aware of any follow up activity and archiving requirements
- **Attending** onboarding-, disease indication and project specific training and general CRA training as required
- **Proactive collaboration** 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
- **Ensuring** 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
- **Participation** in audit organization and inspection readiness activities for monitoring and site related activities as required and ensures implementation of corrective actions within specified timelines
- **Collaboration** with internal stakeholders and site personnel to manage data query resolution process and to ensure timely and accurate data entry
- **Ensuring** 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 of pharmaceutical industry experience or other relevant experience
- 1+ years of field monitoring experience is must, risk-based monitoring experience is desirable
- Excellent time management and organization skills, proven ability to prioritize and multi-task, to adapt in a fast-changing landscape
- Good knowledge of drug development process specifically clinical trial/research, clinical and therapeutic knowledge, knowledge of international standards (GCP/ICH, FDA, EMA)
- Successful in building and maintaining long-lasting relationships
- Excellent communication and presentation skills (oral and written), ability to influence others
- Proven ability to work independently with minimal supervision
- Good analytical thinking
- Solid 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 tostay connected to hear more about Novartis and our career opportunities, join the Novartis Network here:

https://talentnetwork.novartis.com/networkhttps://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

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

部门
Development

Business Unit
Innovative Medicines

地点
Poland

站点
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

Apply to Job

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

Job ID
REQ-10058783

Senior Clinical Research Associate - Poland (home-office)

Apply to Job

Source URL:
https://www.novartis.com.cn/careers/career-search/job/details/req-10058783-senior-clinical-research-

associate-poland-home-office

List of links present in page

1. https://www.novartis.com/about/people-and-culture
2. https://talentnetwork.novartis.com/networkhttps://talentnetwork.novartis.com/network
3. https://www.novartis.com/about/strategy/people-and-culture
4. https://talentnetwork.novartis.com/network
5. https://www.novartis.com/careers/benefits-rewards
6. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Warsaw/Senior-Clinical-Research-Associate---Poland--home-office-REQ-10058783-1
7. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Warsaw/Senior-Clinical-Research-Associate---Poland--home-office-REQ-10058783-1