Clinical Research Associate

Job ID
REQ-10011864
Juli 28, 2024
Australien

Summary

Internal Role Title: Clinical Research Associate

Location: Any city, Australia #LI-Hybrid

About the Role:

CRA role is 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 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.

About the Role

Key Responsibilities :-

- **Frontline liaison between Novartis and sites to ensure successful collaboration, meeting Novartis expectation on achievement and deliverables 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.**
- **Implements site management activities to ensure compliance with protocol.**

- **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**
- **Identify deficiencies in site process, work in close collaboration with site on risk mitigation. Establish a strong a positive relationship collaboration with the site. Early engagement with site on patient inventory and patient flow in advance**
- **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 other relevant business units. Participates in audit organization and inspection readiness activities for monitoring and sit. Collaborates with internal partners and site personnel. Ensures the site Investigator Folder is up to date. Responsible for collecting crucial documents from site and accountable to keep sTMF(s) up to date**

Essential Requirements

- **Degree in scientific or healthcare field. Up to 2 years pharmaceutical industry experience or other relevant experience**
- **Central/in-house monitoring or field monitoring experience is desirable. Decision capability, Excellent time management, organization and risk based attitude.**
- **Early adopter and open attitude across borders to support one**

study approach. Good knowledge of drug development process. Clinical and therapeutic knowledge

- **Knowledge of international standards (GCP/ICH, FDA, EMA).Understanding the purpose of the CRA.**
- **Fast change adaptability to the best partner & influencing with sites on constantly evolving landscape. Trust and rapport building.**
- **Ability to travel domestically. A minimum of 50% overnight travel may be required**
- **Good communication skills, relationship management, excellent communicator, ability to handle sites independently, Good analytical thinking**
- **Ability to anticipate potential issues and take appropriate actions with or without supervision and 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/strategy/people-and-culture

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We are committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and

communities we serve.

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

Division
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New South Wales (NSW)
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Functional Area
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Job Type
Full time
Employment Type
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Shift Work
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