NOVARTIS

Clinical Research Associate

Job ID
REQ-10037007
Jan 16, 2025
Japan

Summary

About the Role

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
Version: 1.0 Date: 1 Jan 2023
Author: SSO Implementation Team, led by Stephanie Visioli
• 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

Education:
• Degree in scientific or healthcare discipline (or, for United States: 4-year degree plus relevant, related healthcare experience).

Languages:
• Fluent in both written and spoken English and country language
Experience/Professional requirement:
• Up to 2 years pharmaceutical industry experience or other relevant experience
• Central/in-house monitoring or field monitoring experience is desirable

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

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf

Accessibility and Accommodation:

Novartis is 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 recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.china@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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Division
Development

Business Unit
Universal Hierarchy Node
Location
Japan
Site
Toranomon (NPKK Head Office)
Company / Legal Entity
JP05 (FCRS = JP005) Novartis Pharma K.K.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

midcareer-r.japan@novartis.com

Job ID
REQ-10037007

Clinical Research Associate

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