

Clinical Research Associate

Job ID
REQ-10037007

1月 16, 2025

Japan

摘要

臨床研究サイトおよび臨床試験参加に関する患者データおよび研究関連情報を監視します。調査員が研究プロトコル、規制要件、良好な臨床慣行に従い、データ検証計画への入力を提供します。患者データのタイムリーかつ正確なモニタリングと、ソースドキュメント、研究記録、およびサイト訪問から、必要に応じて調査関連情報を提供します。調査サイトおよび監査施設の選択を監視できます。

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

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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

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部门
Development

Business Unit
Innovative Medicines

地点
Japan

站点

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

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