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
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/novartiscom/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.

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. You can follow us via Novartis Recruitment WeChat Official Account and Novartis Recruitment WeChat Video Account.

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
Universal Hierarchy Node

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

Apply to Job

利便性と合理的配慮

ノバルティス は 障害 を 持 つ 個人 と 協力 し、合理的配慮 を 提供 することをお 約束 します。健康状態 や 障害 を 理由 に 採用 プロセス のいかなる 部分 においても、あるいは 職務 の 必須事項 を 果 たすた めに 合理的配慮 が 必要 な 場合 は midcareer-r.japan@novartis.com 宛 てに 電子 メール をお 送 りください。その 際 ご 依頼内容、ご 連絡先、求人票 の 番号 を 明 してください。

Job ID
REQ-10037007

Clinical Research Associate

Apply to Job

Source URL:
https://prod1.novartis.com.cn/careers/career-search/job/details/req-10037007-clinical-research-associate-ja-jp

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://www.novartis.com/sites/novartiscom/files/novartis-life-handbook.pdf
3. mailto:diversityandincl.china@novartis.com
4. https://talentnetwork.novartis.com/network
5. https://www.novartis.com/about/strategy/people-and-culture
6. https://talentnetwork.novartis.com/network
7. https://www.novartis.com/careers/benefits-rewards
8. https://novartis.wd3.myworkdayjobs.com/ja-JP/NovartisCareers/job/Toranomon-NPKK-Head-Office/Clinical-Research-AssociateREQ-10037007-1
9. mailto:midcareer-r.japan@novartis.com
10. https://novartis.wd3.myworkdayjobs.com/ja-JP/NovartisCareers/job/Toranomon-NPKK-Head-Office/Clinical-Research-AssociateREQ-10037007-1