Clinical Research Associate

Job ID
REQ-10051625

Jul 10, 2025

Italy

Summary

Job Description Summary
The Clinical Research Associate ensures 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 in 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

Your key responsibilities:

Your responsibilities include, but are not limited to:

- 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.
- 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.
- 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.

Essential requirements:

- Degree in Scientific disciplines.
- At least 1-year experience as a CRA in a pharmaceutical company or CRO.
- Fluent in Italian. Good knowledge of English (B2 level).
- Willingness to travel across the whole country (Italy).

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部門
Development

部門
Universal Hierarchy Node

国
Italy

勤務地
Field Force (Italy)

Company / Legal Entity
IT08 (FCRS = IT008) Novartis Farma S.p.A.

Functional Area
Research & Development

職種
Full time

雇用形態
Regolare

Shift Work
No

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