Clinical Research Associate

Job ID
REQ-10023892
nov 08, 2024
Italie

Résumé

Monitora i dati dei pazienti e le informazioni relative allo studio relative ai siti di studio clinico e alla partecipazione agli studi clinici.. Assicura che il ricercatore aderisca ai protocolli di ricerca, ai requisiti normativi e alle buone pratiche cliniche e fornisce input nel piano di convalida dei dati. Fornisce un monitoraggio tempestivo e accurato dei dati dei pazienti e delle informazioni relative allo studio da documenti di origine, registri di ricerca e visite in loco, ove applicabile. Può monitorare i siti di studio e la selezione delle strutture di audit.

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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Functional Area
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