

Senior Clinical Research Associate

Job ID
REQ-10015289
Jul 23, 2024
India

Summary

100,000+ That's how many patients participate in our clinical trials at any given time. GCO is Novartis' powerhouse of Global Clinical Operations, redesigned to enable faster trial recruitment and enhanced trial delivery resulting in more timely access for patients to potential novel treatments. Every day, we are the link between science and medicine – imagine the impact you could have.

About the Role

Job Purpose:

Site relationship management role to ensure 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 (from issue management to risk identification).

Senior Clinical Research Associate (sCRA) is assigned to more complex trials and/or to less experienced sites where applicable. Associate takes on the responsibility as SME (Subject Matter Expert) as needed, 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, and participates in multi-disciplinary teams locally and globally to evaluate and implement process improvements.

- 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. 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

Activities & Interfaces How does this role operate within, interact with and impact the organization. Externally facing role with impact on Principal Investigators and Institution/Site business offices. Proactively collaborates with the SSO Clinical Project Manager (CPM) and CRA Manager as well as MSL, CRMA and medical advisor and site relationship manager to achieve key accountabilities. Actively share insights with relevant internal stakeholder to drive site and account development. Partners with SSU CRA to ensure seamless transition of site responsibility.

Role Requirements:

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:

- Minimum 3 years pharmaceutical industry experience or other relevant experience

Competencies:

- Decision capability. Excellent time management and organization capabilities, including ability to prioritize and multi-task. Risk based mindset (from issue management to risk identification) supported by Novartis systems. Early adopter and open mindset across borders to support one study approach. Good knowledge of drug development process specifically clinical trial/research
- Clinical and therapeutic knowledge. Knowledge of international standards (GCP/ICH, FDA, EM. Understanding the purpose of the CRA (Patient Safety; Data Integrity; PI oversight; GCP/ICH & Protocol Compliance)

Why Novartis:

Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <https://www.novartis.com/about/strategy/people-and-culture>

Commitment to Diversity & Inclusion: We are committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook.

<https://www.novartis.com/careers/benefits-rewards>

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: <https://talentnetwork.novartis.com/network>.

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>

Division

Development

Business Unit

Innovative Medicines

Location

India

Site

Delhi (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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