

## Clinical Research Associate (CRA)

Job ID  
REQ-10012346

Oct 09, 2024

United Kingdom

### Summary

We are hiring Clinical Research Associates in Study & Site Operations within Global Drug Development (GDD). This is a site relationship management role to ensure sustainable trial execution at Site. The CRA performs on-site and remote monitoring activities related to initiation. They will 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. They will also be involved in 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

#### Responsibilities:

- Frontline liaison between Novartis and sites to ensure successful collaboration, meeting

Novartis expectation on milestone and deliverables with true ownership mindset

- Manage assigned study sites, conducting phase I-IV protocols according to the Monitoring Plan and Novartis procedures
- Perform 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-train site personnel as appropriate
- Conduct continuous site monitoring activities (onsite and remote). Implement 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.
- Identify deficiencies in site processes and monitor site processes performed outside the site, work in close collaboration with site on risks mitigation and process improvements
- 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
- 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
- Collaborate with internal stakeholders and site personnel to manage data query resolution process and to ensure timely and accurate data entry

#### Requirements:

- Degree in scientific or healthcare discipline and ideally 1-2 years pharmaceutical industry experience or other relevant experience.
- Good knowledge of drug development process specifically clinical trial/research
- Clinical and therapeutic knowledge
- Central/in-house monitoring or field monitoring experience is desirable
- Knowledge of international standards (GCP/ICH, FDA, EMA)
- Excellent time management and organization capabilities, including ability to prioritize and multi-task
- Ability to travel domestically (and possibly internationally) as needed to study sites and for training and meetings.
- Fluent in both written and spoken English. Excellent communicator and presenter, ability to influence others & Relationship management
- Ability to manage sites independently; Proven ability to work independently with minimal supervision
- A full UK driving license.

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.

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Division  
Development

Business Unit  
Innovative Medicines

Location  
United Kingdom

Site  
Field Force (England / Wales)

Company / Legal Entity  
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Functional Area  
Research & Development

Job Type  
Full time

Employment Type  
Regular

Shift Work  
No

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