# Study Start-Up Clinical Research Associate

Job ID
REQ-10030678
nov 20, 2024
Canada

## Résumé

Location: Montreal, #LI-Remote

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

We are seeking an innovative, experienced, and agile start-up CRA who is driven by accelerating the start-up of globally run clinical trials and who is motivated in making a difference in reimagining medicine.

About the role:
The Study Start-Up CRA is accountable for site selections as well as study-specific start-up activities and deliverables of assigned sites for 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 preparation and early identification of real site needs and issues and close handover to execution CRA for all sites is key (from issue management to risk identification).
This role will work directly with the local clinical research team and reports to the SSU Team Lead.

## About the Role

**Key responsibilities:**

- Supports country SSU strategy in close collaboration with SSO Study Start-Up Team Lead, SSO Study Start-Up Manager, SSO Feasibility Manager as well as SSO Site Partnership Manager
- Collaborates with SSO Study Start-Up Manager, SSO Study Start-Up Team Lead and global study team to ensure Study Start-Up timelines and deliverables are met according to country commitments
- Accountable for timely start-up activities from country allocation until site greenlight at assigned sites
- Conducts site selection visits, verifies site eligibility for a specific study
- Main contact for trial sites during site selection, study start-up and IRB/IEC and HA submission preparation
- Ensures that milestones (KPIs) and time schedule for study start-up are met as planned
- Supports SSU Manager in preparation of country-specific documents, e.g., ICF, patient facing materials, etc.
- Supports SSO Study Start-Up Manager and assigned sites in vendor set-up activities
- Implements innovative and efficient processes which are in line with Novartis strategy
- Ensures sites are prepared for “Green Light” and is accountable to send the Green Light to SSU Manager for review and approval

**What you'll bring to the role:**

**Essential:**

- A degree in scientific or health discipline, preferably with clinical operations experience
- Minimum 3 years' experience in clinical operations in a monitoring / site management role
- Advanced understanding of all aspects of clinical drug development with particular emphasis on trial set-up, execution, and monitoring
- Strong site management capabilities with demonstrated negotiating and problem-solving skills
- Advanced understanding of the international aspects of drug development process, including strong knowledge of international standards (GCP/ICH), health authorities (FDA/EMA), local/National Health Authorities regulations and Novartis standards
- Bilingual:  English and French

**Desirable**:

- Central/in-house monitoring or field monitoring experience

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representative of the patients and communities we serve.

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