

Study Start-Up Clinical Research Associate

Job ID
REQ-10030678
Nov 20, 2024
Canada

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

Role Requirements

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>

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Division

Development

Business Unit

Innovative Medicines

Location

Canada

Site

Montreal

Company / Legal Entity

CA04 (FCRS = CA004) NOVARTIS PHARMA CANADA INC.

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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