# Clinical Trial Associate

Job ID
REQ-10036835

1月 17, 2025

Canada

## 摘要

Location: Montr é al, #LI-Hybrid
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 Clinical Trial Associate (CTA) 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 CTA supports SSO Study Start-Up Manager and SSO Clinical Project Manager in assigned studies during set-up and whole study lifecycle in compliance with Novartis processes, GCP/ICH and regulatory requirements.

This role will work directly with the SSO Study Start-Up Manager and SSO Clinical Project Manager team and reports to the SSO Start-Up Team Lead.

## About the Role

**Key responsibilities :**

- Supports document collection, preparation, and adaption for submission to IRB/EC and Health Authorities as applicable
- Sets-up systems
- IF and TMF management (country and site TMF); set-up and maintenance according to regulatory and Novartis requirements; document oversight and tracking
- Supports Vendor set-up as applicable
- Checks site "Green Light" completeness and ensures all documentation is in place for initial and subsequent drug release in collaboration with the local Qualified Person(s)
- Supports preparation and translation of ICF into local languages (including vendor management if necessary)
- Supports country SSU strategy in close collaboration with SSU Team Lead and SSU Managers to ensure SSU timelines and deliverables are met according to country commitments
- Ensures adherence to financial standards, prevailing legislation, ICH/GCP, IRB/IEC, Health Authority and SOP requirements
- Provides logistic support to SSU CRA, CRA, CPM, SSU Manager in all phases of the clinical trial
- Implements innovative and efficient processes which are in line with Novartis strategy

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

**Essential:**

- Commercial or medical training (e.g., vocational qualification, bachelor ' s degree), Medical records administrator or equivalent education, preferably with experience in clinical operations
- Fluent in both written and spoken English, local language as needed

- Understanding of clinical drug development with particular emphasis on trial set-up, and contracting
- Profound knowledge of MS Excel, MS Word, MS PowerPoint
- 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

**Desirable**:

- Ideally several years of working experience with 1+ years ´ of experience in clinical operations

**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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部门
Development

Business Unit
Innovative Medicines

地点
Canada

站点
Montreal

Company / Legal Entity
CA04 (FCRS = CA004) NOVARTIS PHARMA CANADA INC.

Functional Area
Facilities & Administration

Job Type
Full time

Employment Type
Regular

Shift Work
No

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