

Study Start-Up Manager

Job ID
REQ-10063878

10月 15, 2025

Canada

摘要

Location: Montreal/Toronto, #LI-Hybrid

Study Start-Up Manager (focus on RLT)

This position is primarily designed to provide strategic and operational support for the implementation of clinical studies involving Radioligand Therapy (RLT) across Canada and US. While formally structured as an SSU Manager role, it does not include regulatory or traditional study management responsibilities. The focus is to serve as a dedicated resource for the expansion and enablement of RLT studies, considering the varying levels of experience and readiness across the region.

About the Role

Key responsibilities:

- Support the mapping and structuring of Central Radiopharmacies in Canada and US, including vendor qualification and contract negotiation support.
- Support the contracting of specialized vendors and provide legal coordination for technical agreements and contracts.
- Act as a regional point of contact for nuclear medicine infrastructure, including equipment, suppliers, and radiolabeling processes.
- Collaborate with local and global stakeholders to ensure the technical and operational feasibility of RLT studies.
- Identify gaps and propose solutions to enhance the country's readiness and capacity for conducting radiopharmaceutical studies.
- Assist studies in securing RLT supplies, supporting with vendor process excellence during Study Start-Up (SSU) and throughout trial conduct.
- Partner with SSU, Clinical Operations, Legal, Quality, Procurement and Regulatory Affairs teams, without assuming direct responsibilities from these areas.
- Contribute to the development of regional playbooks, procedures and best practices for RLT studies.
- Oversight of selection, qualification, & management of Radiopharmacy (both central and site) activities
- Oversight of management of nuclear medicine equipment related tasks (i.e. Dose Calibrator calibrations, Gamma Counter calibrations, SPECT/CT qualifications, PET/CT qualifications, procurement of equipment)

Essential Requirements:

- Bachelor's degree in Pharmacy, Biomedicine, Biomedical Engineering, Medical Physics, or related fields.
- Solid knowledge of radiopharmacy and nuclear medicine, including cold kit radiolabeling processes and operation of equipment such as gamma cameras, PET/CT, and hot cells.
- Familiarity with local and international regulations applicable to radiopharmaceuticals and basic knowledge of compliance and quality standards relevant to clinical studies involving radioactive products.
- Experience in mapping and qualifying technical and logistical vendors for radiopharmaceutical studies.
- Understanding of importation, transportation, and storage processes for radioactive materials.
- Ability to read and interpret technical documents, including product dossiers, safety data sheets, clinical protocols, and technical contracts.
- Strong stakeholder management skills with technical profiles, including clinical engineers, medical physicists, pharmacists, and nuclear medicine specialists.
- Fluent in English and French

Desirable Requirements: (

- Previous experience in clinical research, preferably with exposure to projects involving radiopharmaceuticals or nuclear medicine.
- Strategic mindset and ability to navigate complex and ambiguous environments.

At **Novartis Canada**, we are determined to be a valued partner and advocate, with a deep

understanding of patient needs along the entire care journey - from drug development, to diagnosis, to access and beyond. Part of the way we are doing this is by leveraging data, technology, and partnerships.

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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.

Alternative Location 1
Toronto, Canada

Functional Area
Research & Development

Job Type
Full time

Employment Type
CDI

Shift Work
No

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