

POSITION DESCRIPTION

Title: Study Manager (SM)
Location: North America: Edmonton (Canada)
Supervisor: Global Project Coordinator

Position Overview:

The North American Study Manager is the key person for the coordination in US and Canada of international clinical trials. He (she) assists the Global Project Coordinator (GPC) in the coordination of one or more studies from protocol elaboration to Final Study Report. He (she) is responsible for administrative, logistic and scientific aspects of the study(ies) .

This position reports to the Global Project Coordinator based in Paris. He (she) interacts with study managers, data managers, monitors and central monitoring team, cooperative groups and sponsor (when applicable).

Key Responsibilities:

- Assist the GPC in the definition of objectives and timeline of the study (ies)
- Assist the GPC in the creation of study-related documents (Protocol, Case Report Form (CRF), CRF completion guidelines, validation tool definition, Monthly report, Investigator Newsletter, Final Study Report...)
- Randomize Patients (Verification of the patient eligibility, contacts with the centers in order to resolve logistic and scientific issues)
- Manage the administrative aspects of the study (ies) (Investigator agreement, fee negotiation and payment of the investigators/centers, Planning and organization of supply process (medication, documents), Regulatory key-documents collection, validation and updating)
- Implement the study related processes according to the BCIRG Standard Operating procedures
- Verify the compliance with GCP in study-related tasks
- Verify the data quality (monitoring, validation, Serious Adverse Events)
- Coordinate the study-related monitor activities.

Education and Training:

Scientific background (Nurse, Scientist, Pharmacist, M.D.)

Experience:

At least, 3 years of experience in monitoring or coordination of clinical projects.
Knowledge in oncology and experience in oncology trials are preferred
Fluent English is required.

Skills:

Team spirit, organization and planning, oral and written communication, identification of problems and implementation of solutions, autonomy, able to work in a multi-cultural environment, able to work in a rapid growing and evolving academic group, good informatics knowledge (Word, Excel, Power Point).