IMS Health & Quintiles are now IQVIA

Moving healthcare forward. Together.

We are hiring!

ASSOCIATE SITE MANAGER– with German or French or Norwegian or Italian

#1408829

PURPOSE

Engage in company training program to gain knowledge and skills required to independently conduct clinical remote monitoring visits and other clinical research activities in accordance with study protocol, standard operating procedures, good clinical practice, and applicable regulatory requirements. Gain an understanding of all aspects of Real World Late Phase Research (RWLPR) site management and monitoring by striving to understand the work based on a combination of structured training programs, self-directed use of training materials and experience from study assignments.

RESPONSIBILITIES

- Complete appropriate therapeutic, protocol and clinical research training to perform job duties.
- Gain experience with standard Quintiles tools, metrics and reports.
- Develop an understanding of how sites are staffed and operate in order to build strong relationships with personnel at assigned sites
- Gain experience in study procedures by working with experienced Site Management staff. May also work collaboratively with other functional groups such as Project Management, Regulatory Start-Up (RSU) and Epidemiology.
- Under close supervision, may perform site selection, start-up/regulatory, initiation, monitoring and close out visits in accordance with contracted scope of work, good clinical practices applicable regulations, SOPs and work instructions.
- Under close supervision, administer protocol and related study training to assigned sites and establish regular lines of communication with sites to manage ongoing project expectations and issues.
- Under close supervision, evaluate the quality and integrity of study site practices related to the proper conduct of the protocol and adherence to applicable regulations. Escalate quality issues to Clinical Project Manager (CPM), Site Management Lead (SML) and/or line manager.
- Under close supervision, manage the progress of assigned studies by documenting regulatory submissions and approvals, recruitment and enrollment, Case Report Form (CRF) completion and submission, and data query generation and resolution.
- Under close supervision, create and maintain appropriate documentation regarding site management, monitoring visit findings and action plans by submitting regular visit reports, generating follow-up letters, essential document collection and filing and other required study documentation.

REQUIRED KNOWLEDGE, SKILLS AND ABILITIES

- Awareness of applicable clinical research regulatory requirements; i.e., Good Clinical Practice (GCP) and International Conference on Harmonization (ICH) guidelines
- Computer skills including proficiency in use of Microsoft Word, Excel and PowerPoint
- Strong written and verbal communication skills in applicable languages, and business level command of English
- Basic organizational, interpersonal and problem-solving skills
- Strong attention to detail
- Working time management skills
- Ability to establish and maintain effective working relationships with coworkers, managers and clients and site personnel at assigned sites

MINIMUM REQUIRED EDUCATION AND EXPERIENCE

- Bachelor's Degree in a Life Science is required. Experience in Lifecycle safety (Pharmacovigilance, CEVA, Medical Information, Safety Publishing, Risk Management etc.) is an asset.

PHYSICAL REQUIREMENTS

- Extensive use of telephone and face to face communication requiring accurate perception of speech
- Extensive use of keyboard requiring repetitive motion of fingers
- Regular sitting for extended periods of time
- May require occasional travel

SUMMARY

- The Associate Site Manager is responsible for developing relationship with their assigned clinical trial sites to ensure sites have the information, tools and materials they need to meet the objectives of the study. He/she helps remove roadblocks, answer questions and resolve issues to minimize the burden of study execution on their assigned sites, so site personnel can focus on enrolling patients and capturing data as required by the study.

- The Associate Site Manager is responsible for maintaining regular contact with their assigned sites in accordance with the site monitoring agreement for each study. They collect, compile, document and report site related data. They ensure investigative sites are working in accordance with protocol, standard operating procedures, good clinical practice, and all applicable regulatory requirements. They may be responsible for sites participating in one or more studies, and assignments may include site selection, site initiation and enrollment, follow up and site close out.