World Health Research
GLOBAL RESEARCH SERVICES

Job Description: Clinical Research Monitor & Site Start-Up Specialist (USA):

The World Health Research (WHR) Clinical Research Monitor (CRA) and Site Start-Up Specialist, based in the United States of America supports the study team (project principal investigators (PIs), project manager, project coordinator, and administrative assistant), focused on overseeing and coordinating the initial phases of clinical trial operations, including site identification, feasibility assessments, regulatory submissions, and study initiation activities. As well the position requires monitoring and management of clinical trials to ensure the safety and effectiveness of new and existing drugs and medical devices. The ideal candidate will possess strong organizational skills, attention to detail, and a collaborative mindset.

1. The ideal candidate has knowledge of clinical research principles, regulatory guidelines, and industry best practices.
2. The position requires the ability to work independently as well as collaboratively with cross-functional teams to ensure timely and accurate completion of tasks.

Key Responsibilities:

- Ensure compliance with protocols and Good Clinical Practice (GCP).
- Collaborate with internal and external stakeholders to manage site identification, invitation, selection, and feasibility processes.
- Prepare, review, and submit regulatory documents to ensure compliance with local, regional, and international guidelines.
- Coordinate with clinical sites to facilitate contracts, budgets, and essential document collection.
- Monitor and communicate progress of study start-up activities, identifying and resolving any issues or delays.
- Verify data integrity and documentation.
- Act as the primary liaison between trial sites and sponsors.
- Ensure adherence to timelines, budgets, and regulatory requirements for study start-up activities.
- Maintain and update databases, trackers, and documentation related to study start-up processes.
- Develop regular newsletters and update the study websites.
- Serve as the primary point of contact for study start-up matters for internal and external stakeholders.

Qualifications and Experience:

1. Bachelor's degree in health sciences or a related field.
2. Recent (2 years) experience with clinical trials and/or large research studies, particularly in study start-up activities.
3. In-depth knowledge of ICH-GCP, FDA, and clinical trial guidelines and processes.
4. Strong communication, negotiation, and problem-solving skills.
5. Proficiency in Microsoft Office Suite.
6. Demonstrated strong initiative and drive and the ability to be self directed.

World Health Research: www.worldhealthresearch.ca

The members of World Health Research improve health through important research, education, and advocacy. A beacon of scientific rigour, the company is dedicated to supporting and championing transformative discoveries that reshape the medical landscape.

Please send Resume and Cover Letter to human-resources@worldhealthresearch.ca