

# Global Study Leader

We're hiring a Global Study Leader to work in a multinational biopharmaceutical company in Mississauga, ON.

The Global Study Leader is responsible for leading a cross-functional study team and for providing the team with direction and clear decisions to enable successful delivery of clinical studies from receiving study specifications through to study archiving.

## Summary

- Publication: PUB298369
- Market: LifeSciencesAndHealthCare
- Industry: Pharmaceutical
- Area of expertise: Study & Science
- Hours per week: 40
- Education level: Professional Bachelor
- Closing date: Sunday, 25 April 2021

## Job

## Responsibilities

- You will lead a cross-functional team of experts to operationally deliver defined clinical studies or assigned clinical project activities to time, cost and appropriate quality in line with ICH/GCP and relevant SOPs
- As project leader, you are the point of contact to the CRO project manager to ensure delivery to time, quality and cost; ensuring that appropriate oversight of the CRO is defined and performed across relevant functions for outsourced studies.
- You will develop and maintain up to date study plans (e.g. global study management plan, monitoring plan, etc.) lead study level performance against agreed upon plans, and lead proactive risk and contingency planning and raise issues to stakeholders as appropriate
- You provide input and hold accountability for the development of essential study level documents (i.e. Clinical study Protocol)
- You lead, mentor and support the study team members
- You select and lead vendors, handling their performance to ensure high quality, timely delivered services
- You ensure appropriate training is provided to the local teams, investigators and site staff as well as vendor teams as needed; taking an active role in the Investigators/Monitoring Meetings;
- You set initial operational study budget with the Clinical Program Team (CPT), and are responsible for study budget throughout the study, providing budget progress reports to CPT
- You will ensure studies are inspection-ready at all times, according to ICH-GCP, SOP and relevant policies/guidelines
- You will be responsible for the completeness of the Trial Master File; being the primary Study Management point-of-contact in the event of an audit or inspection
- You may be assigned responsibility for leadership or participation in non-drug project work including applying process improvements methods and change management techniques
- You are responsible for collecting and reporting Adverse Events in accordance with company's policies and procedures

## **About you**

### **Requirements**

- University degree (or equivalent), preferably in medical or biological sciences or discipline associated with clinical research

- At least 7 years of relevant clinical experience in the pharmaceutical industry, or a similar organization (e.g. CRO) including clinical trial leadership experience
- Deep understanding of clinical operations and study management processes, along with experience with the clinical/drug development process in various phases of development and therapy areas
- A minimum of 2 years of global clinical project management experience. PMP certification is desirable but not mandatory.
- You possess strong abilities in cross-functional team leadership, driving personal and team accountabilities, working collaboratively, critical thinking, decision-making, and influencing
- You have proven understanding of clinical study budget management
- Good communication and relationship building skills, including vendor management skills

## **What we offer**

Why apply through Brunel? Finding the next step in your career can be a fulltime job in itself. We manage the process for you: from submitting your resume to coordinating interviews to extending offers and assisting with on-boarding. We'll get you going while you get on with the job.

## **Feel free to contact**

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