Sr. Local Trial Manager â€“ US Home based

Ref #: 29770

Employment type: Permanent â€“ Full-Time

Location: US-Remote

Posted: 01-Nov-2021

Description

DOCS is searching for Trial Managers with experience managing US trials for a Pharmaceutical company. Candidates will have a minimum of 2 years of clinical trial management experience and overall 6 years or more of clinical research experience. Solid Tumor Oncology trials experience preferred.

Description:

â€¢ Sr. LTM is responsible for country do-ability (if applicable) and site feasibility assessment in conjunction with CTA (if applicable), SM and GTM.

â€¢ Implements any local criteria for site selection. Ensure consistent conduct of pre-trial assessment visits and instruct teams on appropriate follow-up of pre-trial visit report and country feasibility report. Recommends suitable sites for selection to participate in trial.

â€¢ Contributes input to the Trial Plan, Safety Monitoring Plan, Filing and Archiving Plan and Investigational Product documents at a country level or initiates development of these plans for a single country trial.

â€¢ Leads and coordinates local trial team activities in compliance with GCO Standard Operating Procedures (SOP), Work Instructions (WI) and applicable regulations. Leads local project planning activities to meet recruitment targets and to deliver high quality data on time and within study budget. Including but not limited to: development of local trial specific procedures and tools, recruitment planning, contingency and risk management, and budget forecasting.

â€¢ Uses study tools and management reports available to analyze trial progress.

â€¢ Monitors country progress and initiates corrective and preventive actions when the trial deviates from plans and communicates study progress and issues to study management teams.

â€¢ Forecasts and manages country/local trial budget to ensure accurate finance reporting and trial delivered within budget.

â€¢ Adheres to finance reporting deliverables and reviews and approves Monitoring Visit Reports submitted by SM; identifies issues and/or trends across a trial project and escalates deviation issues to the GTM and FM as needed

â€¢ May lead negotiation of trial site contracts and budgets. Forecasts and manages country/local trial budget to ensure accurate finance reporting and trial delivered within budget.

â€¢ Actively contributes to process improvement; training and mentoring of Clinical Trial Administrators, Site Managers and other LTMs.

Qualifications:

â€¢ A minimum of a BA/BS degree is required. A degree in a health or science related field is preferred.

â€¢ Minimum six years of pharmaceutical and/or clinical trial experience is preferred. Minimum of 2 years of clinical trial management experience for a pharmaceutical/CRO.

â€¢ Experience managing Solid Tumor Oncology trials is preferred.

â€¢ Should have solid understanding of the drug development process includingICH/GCP and local regulatory requirements.

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DOCS is the FSP division of ICON Clinical Research. We provide global strategic resourcing and FSP services to the biopharmaceutical and medical device industries. Founded in 1997,DOCS has grown to become the premier resourcing provider for the clinical development industry.

DOCS is an equal opportunity employer â€“ Minorities/Females/Disabled/Veterans and committed to providing a workplace free of any discrimination or harassment