Job Title
Project Review Lead (3 years contract)

About STCC
The Singapore Translational Cancer Consortium (STCC) is a nationally coordinated consortium to synergise cancer research capabilities in Singapore. Established in 2020, STCC brings together unmatched basic, clinical and translational talent in Singapore to create globally significant peaks of excellence in selected Asian cancers. STCC's four joint platforms – Clinical Trials and Investigational Medicine Units, Cancer Database and Tissue Banks, Research-based Molecular Diagnostics, and Business Intelligence and Development Unit – provide an enabling research and innovation environment driven to foster translational research with meaningful outcomes for society. We currently have the following opening and would like to invite you to be part of an ongoing and dynamic team.

Job Purpose:
You will manage the progress of assigned studies and trials, including developing study monitoring plans for clinical trials, as well as manage timelines for submissions and approvals. You will also administer protocol and study quality training to the sites conducting the trials.

Job Description
- Prepare the dossier for initial submission, amendment and annual progress reports to ethics committees and regulatory authorities
- Manage the progress of assigned studies by tracking regulatory and ethics submissions approvals, renewal timelines, and recruitment for all sites
- Track the submission and acknowledgement of adverse events and protocol deviations to ethics committees and regulatory authorities
- Develop study monitoring plans for clinical trials conducted in STCC. Ensure that the monitoring of studies in STCC are performed in accordance to the study monitoring plan with quality.
- Conduct SIV training and ad-hoc trainings to sites.
- Independently administer protocol and related study quality training to site and establishes regular lines of communication with sites to manage ongoing project expectations and issues.
- Perform all tasks required for efficient onsite and remote monitoring including but not limited to source document review (SDR) and source document verification (SDV).
- Assess factors that might affect subject's safety and clinical data integrity related to the proper conduct of the protocol and adherence to applicable regulations.
- Create, submit and maintain appropriate documentation regarding site management, monitoring visits, findings, and action plans (eg. regular visit reports and other required study documentation)
- Review data recorded in source documents for accuracy and completeness and in accordance with the study monitoring and associated plans.

- Maintain all areas of cover as assigned (study level) to audit readiness standards and supports preparation for audit and required follow up actions.
- Perform investigational product (IP) inventory, reconciliation and reviews storage and security. Manage any other IP related matters according to Health Product Act.
- Set up, maintain and routinely reviews the trial master file (TMF) and Investigator Site File (ISF) for accuracy, timeliness and completeness.
- Conduct training on the use of the randomization system and clinical database
- Liaise with the site on the data entry and cleaning process for data analysis by the data monitoring committee
- Oversees study conducted at the site, provides advice to sites to ensure smooth site preparation and running of study within timelines
- Assist Investigator in site audit/inspections by ethics or regulatory body.
- Manage timely site monitoring and site close-out activities as per the study monitoring plan till trial completion.
- Prepare study status updates and trackers/reports to management and sponsoring pharmaceutical companies

Job Requirements

- Possess a minimum of a Bachelor's degree in life sciences, nursing, pharmacy, medical science or equivalent preferred
- At least 3 years of relevant experience, preferably in monitoring of clinical trials in a CRO or industry-related organization. Experience in monitoring oncology trials would be advantageous
- Possess a valid certificate of attendance and in-depth understanding in Good Clinical Practice (GCP), clinical trial monitoring, drug development process, regulatory requirements and basic knowledge of project management and medical terminology.
- Possess demonstrated excellent communication, organizational, time management and problem-solving skills, ability to work independently and in a team
- Resourceful, with good work ethics, meticulous with an attention for details
- Has the ability to be flexible and able to multi-task to meet deadlines
- Proficient in Microsoft office applications

Please send your application to career@cris.sg

Please indicate in your email the following header: Application for Project Review Lead, STCC

Company Overview

The Consortium for Clinical Research and Innovation Singapore (CRIS), a wholly owned subsidiary of MOH Holdings, was established in 2020 with the goal of strengthening synergies and promulgating strategies for national-level clinical research and translation programmes under the stewardship of the Singapore Ministry of Health. The former Singapore Clinical Research Institute Pte Ltd was repurposed to form CRIS which brings together five entities as business units under a common management and governance structure. These are the Singapore Clinical Research Institute (SCRI), the National Health Innovation Centre (NHIC), the Advanced Cell Therapy and Research Institute Singapore (ACTRIS), the Precision Health Research Singapore (PRECISE), and the Singapore Translational Cancer Consortium (STCC).

Additional Company Information

Average Processing Time
25 days

Industry
Healthcare / Medical

Benefits & Others

Dental, Miscellaneous allowances, Medical, Regular hours, Mondays-Fridays, Business (e.g. Shirts)