Job Title
Senior Clinical Research Associate (3 years Renewable contract)

About SCRI
The Singapore Clinical Research Institute (SCRI) is the national coordinating body (NCB) for clinical trials with a vision to establish Singapore as a regional thought leader in clinical research. This is accomplished through the deployment of innovative technologies and processes, and strategic coordination of ecosystem capabilities and infrastructure to achieve synergies that will enhance the clinical research ecosystem aimed towards a healthier community and better patient outcomes.

The Role:

You will support the monitoring of investigator sites and trial execution within SCRI and mentor Clinical Research Associates (CRAs). You will also be responsible for planning and managing of clinical trial activities which will include:

- Support in the management of designated clinical trial activities including preparation of trial related documentation and study files, organizing Ethics Committee and Regulatory submissions, progressive and site/study closeout reports with follow through to ensure successful outcome
- Participate in assigned site training activities e.g. investigator meeting and study site initiation meetings
- Facilitate preparation of site and sponsor documents for study conduct and related activities
- Maintain project files including: Ethics Committee approvals and/or acknowledgements; curriculum vitae of investigators and study personnel; clinical investigators brochure; protocols; case report forms instructions; consent documents; clinical trial material shipping orders; start-up meeting attendance documentation; letters of agreement; lab reference ranges; all investigator and site correspondence; monitoring related reports; SAE reports and schedules of payment
- Facilitate clinical trial management including site drug supply management. Assist in planning the requirements for clinical trial material, ordering clinical trial (CT) materials, setting up and monitoring the systems for shipment of CT material to the investigator, maintaining procedures to account for CT material, checking the expiration of CT material and requesting extensions if necessary, checking the storage of Investigational Product (IP).
- Be the point of first contact when investigators/site personnel enquire about patient inclusion/exclusion criteria for ongoing trials
- Act as field monitor for assigned sites on a clinical study. Perform monitoring visits in accordance to study specific monitoring plan including source document verification, drug accountability checks, etc according to ICH GCP and company SOPs
- Prepare site initiation, study monitoring and closeout reports for review and send out within timelines.
- Ensure site activities are in line with milestones (i.e. startup, recruitment, closeout)
- Perform SAE processing activities including reconciliation as per ICH GCP and company SOPs.

Consortium for Clinical Research and Innovation, Singapore Pte Ltd (Reg No: 200812355Z)
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23 Rochester Park, #06-01, Singapore 139234 | Tel: (65) 6508 8300 | Fax: (65) 6508 8317

- Assist in the review of Case Report Forms (CRF) and CRF completion guideline. Assist with data query resolution process (both at Site and with Data Management). Ensure that queries generated during cleaning are responded to in a timely fashion.
- Assist in issue resolution promptly and share best practices with site(s) and company colleagues
- Demonstrate and apply ICH GCP, applicable local regulatory requirements and Ethics
- Committee SOPs and company SOPs
- Participate and lead in SOP development, process initiatives and assigned training initiatives/activities
- Lead and coach team members on assigned studies and SAE processing

Requirements:

- A healthcare or scientific discipline (e.g. pharmacy, life sciences, nursing or other related area) or relevant experience working in medical, QA, regulatory, safety, training or pharmaceutical company or equivalent
- Knowledge of clinical trial monitoring, drug development process, GCP, regulatory requirements of regional countries, basic knowledge of project management and medical terminology.
- Preferably have passed ACRP CRA examination
- Demonstrates strong ability to prioritise, coordinate, organise, communicate and lead
- Excellent understanding of clinical development process including ICH GCP fundamentals
- Proven ability to work independently and in teams and deliver commitments on time
- Computer literacy

Please send your application to career@cris.sg

Please indicate in your email the following header: **Application for Senior/Clinical Research Associate (SCRI)**

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

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Average Processing Time
25 days

Industry
Healthcare / Medical

Benefits & Others
Dental, Miscellaneous allowances, Medical, Regular hours, Mondays-Fridays

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