

Job Title : Project Coordinator (Clinical Trials)

Department : STCC - Clinical Trials and Investigational Medicine Units

Business Entity: STCC

Overview

The Consortium for Clinical Research and Innovation, Singapore (CRIS) brings together five national R&D, clinical translation and service programmes to advance clinical research and innovation for Singapore, and establish important capabilities for a future-ready healthcare system. The Business Entities under CRIS include:

- Singapore Clinical Research Institute (SCRI)
- National Health Innovation Centre (NHIC)
- Advanced Cell Therapy and Research Institute, Singapore (ACTRIS)
- Precision Health Research, Singapore (PRECISE)
- Singapore Translational Cancer Consortium (STCC)

Together, CRIS makes a positive difference to Singapore patients and researchers by ensuring that these clinical research platforms and programmes are at the cutting edge of capability development and innovation. If you are as passionate as we are in clinical trials and research, we want you!

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.

What you will be working on

The Role:

The Project Coordinator (Clinical Trials) will be responsible for the duties and responsibilities listed below:

Primary Responsibilities and Duties

- Assist to draft and collect the study documents required for dossier submission to Institutional Review Board (IRB) and to the Health Sciences Authority (HSA).
- Track regulatory and ethics submissions, approvals and renewal timeline, submission and acknowledgement of adverse events and protocol deviations to ethics committees and regulatory authorities.
- Assist with feasibility assessments.

- Assist with review and execution of non-disclosure agreements, clinical trial agreements and research collaboration agreements with pharmaceutical/biotech companies, participating sites and vendors.
- Maintain and update feasibility tracker (list of feasibility requests) and database (frequently asked questions and answers repository).
- Assist to draft the site budgets and liaise with pharmaceutical/biotech companies and sites.
- Manage user access and issues for randomization system and clinical database.
- Assist with the creation of case report form and set up of database for assigned clinical trials.
- Liaise with the data manager, study monitor and the sites on the progress for data entry and cleaning.
- Set up, maintain and routinely review the electronic and hardcopy trial master file for accuracy, timeliness and completeness.
- Coordinate the distribution of SUSAR reports from the pharmaceutical/biotech companies to the sites for regulatory and ethics submission.
- Coordinate the logistics of laboratory activities between the central laboratories and the sites, track the biological samples sent to central laboratory and stored at all sites.
- Coordinate the procurement, purchasing and delivery of clinical trial services and investigational products, shipments of consumables and samples
- Monitor the investigational product inventories and activities according to trial SOPs at the site pharmacy
- Liaise with stakeholders (sites, CROs and vendors) to track/manage invoicing and payment matters.
- Update and maintain internal databases and tracking systems with project specific information.
- Coordinate and prepare materials and meeting minutes for trial meetings with internal and external stakeholders.
- Prepare study status updates and trackers/reports to management and sponsoring pharmaceutical companies.
- Coordinate and support STCC tumour groups related activities which include preparation of documents and facilitation of meetings.
- Assist in the review of the clinical trial protocol and study-related documents such as pharmacy manual, laboratory manual, drug request forms, SAE forms, study file templates, monitoring visit templates, etc.

What we are looking for

Qualification

 Minimum Bachelor's degree in life sciences, nursing, pharmacy, medical science or equivalent preferred.

Experience

- At least 1 year of experience in clinical research in a Pharmaceutical Company, or CRO.
- Possess knowledge of Good Clinical Practice (GCP), clinical trial monitoring, drug development process, regulatory requirements and basic knowledge of project management and medical terminology.

Skills

- Proficient in Microsoft Office e.g. PowerPoint, Word and Excel
- Meticulous with an attention for details.
- Good interpersonal and communication skills
- Flexibility and ability to multi-task and meet deadlines.

What you need to know

Successful candidate will be offered a 3-year renewable contract. Please send your application to career@cris.sg with the subject **Application for** Project Coordinator (Clinical Trials), STCC. We regret that only shortlisted candidates will be contacted. For more information about CRIS and the Business Entities, visit our websites below:

- o CRIS https://www.cris.sg
- o SCRI https://www.scri.edu.sg
- NHIC https://www.nhic.sg
- o ACTRIS https://www.actris.sg
- PRECISE https://www.npm.sg
- o STCC https://www.stcc.sg