Job Title : Assistant Study Manager /Study Manager
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 Assistant Study Manager / Study Manager (Clinical Trials) will be responsible for the duties and responsibilities listed below:

Primary Responsibilities and Duties

- Manage and liaise with Investigators on their interest in the feasibility requests received.
- Perform appropriate trial feasibility assessment and determine risk mitigation strategies and steps.
- Prepare and review feasibility questionnaires, surveys and other feasibility-related documents.
- Create, maintain and update feasibility tracker and database
- Evaluate, document and collect information on sites and other available facilities.

- Contribute and manage processes related to continuous quality improvement and effective feasibility evaluation and site identification.
- Prepare and coordinate documents from relevant stakeholders for regulatory and ethics submissions.
- Manage the regulatory and ethics submissions and approvals for assigned clinical trials.
- Manage the review and execution for the non-disclosure agreements, clinical trial agreements, research collaboration agreements as well as manage and liaise with pharmaceutical/biotech companies and sites on the budget negotiations.
- Prepare, review and monitor the status of submissions/amendments for regulatory authorities and ethics committees. Ensure adherence and compliance with regulation and internal procedures.
- Execute all start-up related activities.
- Assist with the creation and review of the case report form and set up of database for assigned clinical trials.
- Liaise with stakeholders (sites, CROs and vendors) to set up invoicing and payment matters.
- Arrange and coordinate STCC tumour groups related activities which include development of documents and facilitation of meetings.
- Update and maintain internal databases and tracking systems with project specific information.
- 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 3 years 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, project management and medical terminology.
- Able to conduct literatures searches and interrogate databases.

Skills

- Proficient in Microsoft Office e.g. PowerPoint, Word and Excel
- Meticulous with an attention for details.
- Excellent communication skills, both written and spoken.
- strong communication, time management, analytical and problem-solving skills.
- Ability to work independently and in a team.

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** Assistant Study Manager / Study Manager (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:

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