

Clinical Research Coordinator

LEVEL 2

Programme



□ DURATION

6 Days over 3 weeks Thursday and Fridays



coordination.

COURSE FEES



Investigator-Initiated Trials (IIT) Made Easy for CRC

"If you fail to plan, you are planning to fail!" - Benjamin Franklin.

Conducting an investigator-initiated trial requires a lot of planning and

In this programme, you learn about the key fundamental project management concepts and tools that are commonly used in clinical research studies, and ability to coordinate acquire the investigator-initiated clinical research studies with a reasonable degree of proficiency. Applications will reinforced interactive through classroom discussions, case scenarios and practice-based activities.

WHAT YOU'LL LEARN

- Apply project management concepts from site feasibility stage to completion of a study, which includes resources management, track project status and managing quality issues
- Develop study documents such as data collection tools
- Manage research materials, biological specimens and site logistic matters
- Implement the operational workflow and quality systems for the research study
- Explain the IRB and regulatory requirements, and responsibilities for sponsors in an IIT
- Develop the ability to anticipate and mitigate potential risks or non-compliance
- Highlight key concepts for preparing and conducting a study monitoring

- **Fundamentals of Project Management**
- Application of Project Management Knowledge on Site Feasibility
- **Project Organisation Structure**
- Research Grants Management
- Resource Management and Study **Budget**

Project Management

- Development of Study **Documents**
- Protocol Review
- Study Template Design
- Data Collection & Management
- Management of Trial Master File

Programme

Responsibilities of Sponsor PI in Investigator-initiated Multicenter Trial

- **Quality Management Systems**
- QC: Study Monitoring
- IRB and Regulatory requirements
- Be Audit/Inspection Ready
- Site Readiness for Closure

Outline

Quality

- **Operational** Workflow
- **Recruitment Strategies**
- Management of Clinical Research Materials
- Management of Biological Specimens
- Organise IM and SIV; Training of Study Personnel
- Safety Monitoring

Who Should Attend

- Senior CRCs
- CRC with job responsibilities equivalent of a Senior CRC
- CRC who is progressing towards Senior CRC iob grade

Entry Requirements

All requirements must be met:

- · At least 5 years of experience in coordinating clinical research studies
- experience in subject recruitment. Has informed consent and/or subject follow-up
- · Has basic understanding of clinical research, such as IRB requirements, ICH Good Clinical Practice, source documentation, essential documents, safety reporting and management of investigational product.

Application Procedure

To register for the CRC Level 2 Programme, applicants and their supervisors must complete the following electronic forms.

REGISTRATION PERIOD:

Applicant's Form

Supervisor / Reporting Officer Form



Registration priority will be given to CRCs corefunded under the NMRC CRC programme, and CRCs from Singapore's public healthcare institutes under MOH Holdings.

For more information on this programme, please visit SCRI website: https://for.sg/level2

Testimonials

The six-day Clinical Research Coordinators (CRC) Level 2 programme involves many experienced speakers. I really like the classroom discussions and group activities as I gained new knowledge and insights on project execution and management. The programme is a great platform for me to get to know other peers from other healthcare institutions. Through daily practicebased activities, we also get to share our diverse knowledge and experiences with one another. I strongly recommend all eligible CRCs to enroll in this course, for you will gain very useful knowledge and skills!" Trish Koon (Clinical Research Coordinator, Division of Obstetrics and Gynaecology, KK Women's and Children's Hospital)

> Contact Us scriacademy@scri.cris.sg

"The SCRI CRC Level 2 Programme instructors were interactive, and they facilitated the programme interestingly through the classroom and case scenario discussion. From the programme, it has motivated me to think in-depth in strengthening my project management skills and coordination. I believe I am able to apply the appropriate knowledge in my course of work."

Su Jialei (Senior Research Nurse, Khoo Teck Puat Hospital)

SCRI CRC Level 2 programme covers a wide range of topics which gives a comprehensive overview of what the expected responsibilities, knowledge and skill sets are required for a senior CRC. The intensive programme also covers a wide range of content and in-class exercises. The instructors are knowledgeable and engaging and sharing of their experiences helps novice senior CRCs like myself connect new knowledge and processes learnt with my everyday work tasks.

Wong Cher Yi (Clinical Research Coordinator, NUHCS)