Clinical Research Coordinator Level 1 Programme (Blended)

Course Description

The Clinical Research Coordinator (CRC) is a specialised research professional working with the research investigator to ensure smooth progress of the research project. The CRC Level 1 Programme (Blended) is designed for CRCs with less than one year of experience and who are interested in gaining knowledge about coordinating clinical trials. The programme offers a comprehensive introduction to the operations of clinical trial at site and practical, hands-on training through the blended learning approach to provide flexible and effective learning. Participants will self-learn through the interactive study materials, followed by face-to-face (F2F) classroom sessions (physical or virtual) to reinforce the application of core CRC skills through classroom discussions, case scenarios, demonstrations and practice-based activities. This programme is also valuable for individuals seeking a new career as a CRC.

The SCRI Academy was launched in August 2017 by the Senior Minister of State (Ministry of Health and Ministry of Transport) to house the training efforts for CRCs. The SCRI Academy is part of the Singapore Clinical Research Institution (SCRI), which is a business unit under the Consortium for Clinical Research and Innovation Singapore (CRIS), a wholly owned subsidiary of MOH Holdings.

This training programme is funded by the Ministry of Health in collaboration with Health Sciences Authority, Singapore Health Services, National Healthcare Group, National University Health System and Nanyang Polytechnic.

Learning Outcomes

- Describe the clinical trial activities from study initiation to closure
- Discuss the importance of Good Clinical Practice
- Understand the investigator and sponsor responsibilities in a clinical trial
- Define the requirements for ethics submissions, source documentation and essential documents
- Discuss the informed consent process
- Discuss strategies for subject recruitment and retention
- Prepare your site for a monitoring visit
- Define safety reporting guidelines
- Describe the process for management of investigational product at site

Who Should Attend

- CRCs with less than one year of experience

Entry Requirements

- At least a Diploma in Biomedical Sciences, Life Sciences, Nursing, Pharmacy or equivalent

Course Duration

- Approximately 3 months / 12 weeks (every Friday), 1:00 pm to 6:00 pm
  (Except for Week Two and Week Twelve which runs from 9:00 am to 5:30 pm.)
- 2 runs a year – March intake, September intake
  ** Please refer to the SCRI Website for the upcoming intake dates.*

Course Location

- Physical F2F Classroom Session: NTU@one-north, 11 Slim Barracks Rise, Singapore 138664
- Virtual F2F Classroom Session: Zoom
  ** Please refer to the SCRI Website for the delivery method of the F2F classroom session of the respective intake – either Traditional or Virtual.*

Course Outline

Week One • Overview of Programme • Introduction to Clinical Trial • Drug Development Process • ICH Good Clinical Practice • Clinical Trial Framework in Singapore • Research Team • Elements of a Protocol • Site Feasibility • Site Start-up Activities and Workflow	**Week Two** *(Full day class)* • Overview of Singapore's Healthcare System • Understanding Medical Records • Health Assessment by Observation • Administration of Medication • Specimen Collection • Documenting real-time progress notes • Effective Communication • Overview of Key Research Therapeutic Areas – Diseases & Investigations* • Common Medical Conditions and Related Medications* • Understanding Eligibility Criteria in Clinical Trials and Related Investigations*
Week Three • Clinical Trial Agreement • Study Budget • Billing and Payment to Sponsor • Ethics Board and Application Process • Investigator Meeting & Site Initiation Visit • Subject Eligibility	**Week Four** • Source Documentation • Essential Documents • Investigator Site File, Tools and Templates • Deviations, Amendments and Reporting • Subject Visits, Follow-up and Retention • Subject Discontinuation • Payment to Subjects • Randomisation & Unblinding
Week Five • Safety Reporting to IRB • Subject Recruitment and Follow-up Documentation • Recruitment Strategies	**Week Six** • Elements of Informed Consent Form • Informed Consent Process & Documentation • Vulnerable Populations and Safeguards • Wavier of Consent in Special Circumstances
Week Seven • Clinical Trial Regulations • Clinical Trial Registry • Clinical Trial Safety • Reporting Adverse Events • Working Effectively with Sponsor & Investigator • Time Management	**Week Eight** • Overview of GCP Inspection • Common Inspection Findings • Notification of Serious Breaches • PRISM

Note: Information is accurate at time of print and is subject to changes without prior notice.

Week Nine	**Week Ten**
• Regulatory Requirements for Clinical Research Materials • Management and Handling of Investigational Product, and Documentation • Drug Dispensing and Accountability	• Central Laboratory • Study Kits • Collection of Biological Specimens, Processing and Shipping • Study Supplies • Monitoring Visit Preparation and Follow-up • Responding to CRF Queries*
Week Eleven	**Week Twelve**
• Site Closure & Close-out Visit • Early Termination of Study & Record Retention	MCQ Examination and Oral Assessment

***** *The module is entirely e-learning based, without face-to-face classroom session. Guidance and support will be provided by the trainers via emails, if required.*

E-Learning Session

Participants will be given access to the e-learning materials one month before and after the F2F classroom sessions. It comprises of the SCRI Academy online learning series titled 'The Essentials of Clinical Trials for Beginners', along with other comprehensive online training materials and pre-class quiz. Participants are required to complete all e-learning videos and quizzes by Week 12 of the programme.

Technical Requirements

This is only applicable if the F2F classroom session is conducted virtually.

It is mandatory to fulfil **ALL** the following minimum technical requirements:

1. Use of PC or Laptop for MCQ Examination, as the system is not compatible on Mobile devices (e.g. mobile phone or tablets). You are also strongly encouraged to access the Zoom virtual class via a PC or Laptop for better learning experience as you need to refer to the training handouts while attending the class.
2. Stable internet connection (3G or 4G/LTE), with minimum bandwidth of 600kbps is recommended. You can check your Internet bandwidth using www.speedtest.net or http://bandwidthplace.com/.
3. Supported browser versions:
    - Windows: IE11+, Edge 12+, Firefox 27+, Chrome30+
    - Mac: Safari 7+, Firefox 27+, Chrome30+
    - Linux: Firefox 27+, Chrome 30+
4. Headphone (preferred) or speaker to listen in (built-in / USB plug-in / wireless Bluetooth)
5. Microphone for class discussion (built-in / USB plug-in / wireless Bluetooth)
6. Webcam (built-in / USB plug-in). It is compulsory to turn on the camera for the duration of the Zoom virtual class for attendance authentication.

Registration Period

- For March Intake: 15 November to 15 January
- For September Intake: 15 June to 15 July

Application Procedure

To register for the CRC Level 1 Programme (Blended), please email your completed Registration Form to scriacademy@scri.cris.sg along with the required supporting documents when the registration opens.

Registration is on a first-come first-served basis and priority will be given to CRCs core-funded under the NMRC CRC programme. Priority will also be given to CRCs from Singapore's public healthcare clusters under Ministry of Health Holdings.

Course Fees

Full Price	$2,895 *(inclusive of 7% GST)*
CRCs from Singapore's Public Healthcare Clusters under MOH Holdings (After 90% subsidy)	$289.50 *(inclusive of 7% GST)*

Qualification

Participants who have completed all modules of the programme and have passed the examination will obtain:

1. E-Certificate of Participation (Essentials in Clinical Practice) from Nanyang Polytechnic,
2. E-Certificate of Achievement (Informed Consent & Subject Recruitment) from National Healthcare Group, and
3. Certificate of Achievement (CRC Level 1 Programme (Blended)) from SCRI Academy

Enquiries

For enquiries, please contact scriacademy@scri.cris.sg.