CLINICAL RESEARCH COORDINATION AND MANAGEMENT MODULE

This module is suitable for anyone involved in planning, conducting, supervising and monitoring clinical research projects or trials.

- Delivered by the RCSI Clinical Research Centre in conjunction with the RCSI School of Postgraduate Studies
- Accredited by the Nursing & Midwifery Board of Ireland for 18 continuing education units. Also accredited for 5 ECTS as part of a postgraduate award within RCSI.
- Delivered online; Registration Fee: €180.00; Certificate awarded on completion of written assignment.
- For more information contact Deirdre Hyland, Director of Research Nurse Education, RCSI CRC. dhyland@rcsi.com

Part 1: Study Set-up

Types of Clinical Research

- Feasibility Assessment
- Study Setup and Administration (Processes, risk assessment, budget)
- Investigator meetings
- Site initiation visits

Part 2: Managing Patient Visits

Role of Study Coordinator

- Patient Recruitment and Screening
- Data entry and Discrepancy Management
- IMP and Resource Management
- Study close-out and archiving

Part 3: Safety and Regulatory Issues

- Setting Up and Managing Investigator Site Files
- Role of the CRA (Monitor)
- Adverse Event Reporting
- Preparing for Audits & Regulatory Inspections
- Documentation in Clinical Research

INTRODUCTION TO CLINICAL RESEARCH AND GOOD CLINICAL PRACTICE (GCP)

Essential training for Principal Investigators, research nurses/midwives, monitors and research site personnel involved in clinical trials of medicines. Content is based on ICH E6 (R2) 2016, and includes key requirements of the Clinical Trial Regulation (536/2014). Includes:

- Introduction to Drug Development and Clinical Research
- Clinical Research Governance & Principles of Good Clinical Practice
- Investigator Responsibilities
- Safety Reporting, Essential Documents & Regulatory Inspection

This course is provided by the RCSI Clinical Research Centre. Due to disruption caused by Covid-19 the course is currently available online only. Review of the content takes 2.25 hours, not including time spent on self-directed exercises and exploring resources. On completion of all sections of the course a Multiple Choice Questionnaire must be passed in order to receive a certificate.

- Cost of completion: €60.00 per person.
- For more information or to make a booking please contact Deirdre Hyland: dhyland@rcsi.com
- The course is accredited by the Nursing & Midwifery Board of Ireland (NMBI). It also meets the minimum criteria for ICH GCP investigator site personnel training identified by TransCelerate Biopharma as necessary to enable mutual recognition of GCP training by trial sponsors

GOOD CLINICAL PRACTICE (GCP) REFRESHER COURSE

Essential training for Principal Investigators, research nurses/midwives, monitors and research site personnel involved in clinical trials of medicines. Content is based on ICH E6 (R2) 2016, and includes key requirements of the Clinical Trial Regulation (536/2014). Includes:

- Clinical Research Governance & Principles of Good Clinical Practice
- Investigator Responsibilities
- Safety Reporting, Essential Documents & Regulatory Inspection

This course is provided by the RCSI Clinical Research Centre. Due to disruption caused by Covid-19 the course is currently available online only. Review of the content takes 1.5 hours, not including time spent on self-directed exercises and exploring resources. On completion of all sections of the course a Multiple Choice Questionnaire must be passed in order to receive a certificate.

- Cost of completion: €40.00 per person.
- For more information or to make a booking please contact Deirdre Hyland: dhyland@rcsi.com
- The course is accredited by the Nursing & Midwifery Board of Ireland (NMBI). It also meets the minimum criteria for ICH GCP investigator site personnel training identified by TransCelerate Biopharma as necessary to enable mutual recognition of GCP training by trial sponsors

GOOD CLINICAL PRACTICE (GCP) IN MEDICAL DEVICE RESEARCH

A one day course aimed at investigators, project managers, research nurses and other research team members involved in the conduct of medical device research at a clinical research site. It is also relevant to sponsors and device manufacturers involved in organising and initiating clinical investigations. Content is based on applicable sections of the Medical Device Regulation and ISO 14155, and includes:

- Principles of Good Clinical Practice in Medical Device Research
- Medical Devices (What is a Medical Device; Types & Classification; Medical Device Legislation; Clinical Investigations)
- Good Clinical Practice (Ethical Considerations; Planning and Conducting a Clinical Investigation)
- Safety Reporting, Monitoring & Audit in Medical Device Research

This course is provided by the RCSI Clinical Research Centre. Due to disruption caused by Covid-19 the course is currently offered as a study day using MS Teams. Cost of completion: €60.00 per person.

- An online version of this course will be available soon!
- For more information or to make a booking please contact Deirdre Hyland: dhyland@rcsi.com