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CRC Program

1. Introduction – The role of CRC 6 hours

   - Supporting investigators with patient recruitment
   - Administrative coordination of ethics committee submissions to hospitals
   - Support of the CRA during monitoring visits
   - Maintenance of the Investigator's file
   - Coordination of patient visit schedules
   - Drug accountability and dispensing logs
   - Coordination of sample shipments
   - Payment of patient expenses
   - Supporting data entry/query resolution/SAE notification

2. New drug discovery 6 hours
   - New drugs
   - Phases of Clinical trials
   - Study design and types of clinical trials

3. Clinical Trials – general terms 6 hours

4. Clinical Trials regulation – Local 3 hours
   - Health Protection Act
   - Drugs and Medical devices Act
   - Rule book on Clinical trials

5. Clinical Trials regulation – International 3 hours
   - EU directives
   - DA
   -

6. GCP 6 hours
   - Basics of GCP
   - Ethics Committees
   - Informed Consent
   - Investigator Responsibilities
   - Sponsor's Responsibilities

7. Site Management 6 hours
   - Startup Activities
   - Documentation
   - Subject Recruitment and Retention
   - Contract Negotiation for Researchers and Sites

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8.	Soft skills - Time management - Communication skills - Stress management - Team work	6 hours
9.	Project management - Study budget and contracts - Investigator payments - Expenses - Quality Assurance	6 hours
10.	Data management and Statistics -CRF -Data Entry -CTMS	6 hours
11.	Safety reporting and PVG in clinical trials - PVG – definitions - Site/Investigator responsibilities - AE intensity assessments - SUSAR	6 hours
•	Business communication in English	30 hours