HRSI clinical monitor curriculum

update: Aug2024

Module	Learning objectives	Content	Learning methods	Time (miniue)	Resources	Evaluation
Module 1 - Principles of research ethics						
Session 1	1. ตระหนักถึงหลักจริยธรรมทั่วไปในการวิจัยที่เกี่ยวข้องกับมนุษย์ 2. ติดตามวิวัฒนาการของหลักจริยธรรมการวิจัย 3. ตระหนักถึงการประยุกต์ใช้หลักการในการทดลองทางคลินิก	Principles of research ethics - Declaration of Helsinki - Belmont Report - CIOMS - WHO 2011	Interactive Power Point presentation	60	ppt as handouts / reference materials	session 22b
Module 2 - Introduction to GCP						
Session 2	1. Recognize the need for GCP 2. Recognize fundamental principles of the Declaration of Helsinki 3. Describe ICH GCP and its principles 4. Describe basic framework of GCP	1. Concept of GCP, Why GCP? 2. History of GCP 3. Declaration of Helsinki 4. Principles of ICH GCP 2016 5. Framework of GCP	Interactive Power Point presentation	60	ppt as handouts / reference materials	session 22b
Module 3 - Stakeholders and their reponsibilities						
Session 3	**Ethics committee/IRBs**: To recognize the role and responsibilities of the Ethics Committee, and the scope of these responsibilities	- Responsibilities of EC/IRB - Composition, function and operation - Procedures - Rapports	Interactive Power Point presentation / Discussion of answers of take home quiz	45	ppt as handouts	session 22b
Session 4	**Investigator**: Recognize the roles and responsibilities of the investigator and the scope these responsibilities	Responsibilities of the investigator according to: - ICH-GCP 2016 - Declaration of Helsinki (2013)	Interactive Power Point presentation / Discussion of answers of take home quiz	45	ppt as handouts / reference materials	session 8 and 22b
Session 5	**Sponsor**: Recognize the roles and responsibilities of the sponsor and the scope of these responsibilities	- Trial design and Trial management - Investigator Selection - Responsibilities related to the Investigational product - Safety information and reporting - Monitoring - Audit - Non compliance - Others sponsor's responsibilities	Interactive Power Point presentation / Discussion of answers of take home quiz	45	ppt as handouts / reference materials	session 8

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Session 6	**Clinical monitor responsibilities**: To recognize the roles and responsibilities of the clinical monitor and the scope of these responsibilities	1. Responsibilities of clinical monitor according to GCP 2. WHO-TDR SOPs on monitoring: - Pre trial visit - Initiation visit - Routine monitoring visit - Close out monitoring visit - Writing monitoring visit report	Interactive Power Point presentation / Discussion of answers of take home quiz	45	ppt as handouts / reference materials	session 22b
Session 7	**Regulatory authorities responsibilities**: - To recognize the responsibilities of Regulatory Authorities during the different phases of product development - To recognize the scope of international and local regulatory requirements	- Pre-licensing regulation; - Post-licensing regulation; - Inspection; - Registration - Pharmacovigilance	Interactive Power Point presentation / Discussion of answers of take home quiz	45	ppt as handouts / reference materials	session 22b
Module 4 - Monitoring						
Session 8	**Site visit** - Hands-on learning of principles of GCP within the context of clinical monitoring – site assessment, pharmacy, laboratory, archiving, data management, CRF review	Pre-study monitoring visit, initiation visit, routine monitoring visits, close out visit	Site visit – review, and inspection of documents; inspection of facilities, meetings and discussions with study team; facilitated by HSRI clinical monitors	315	Study documents / HSRI clinical monitor SOPs	facilitator's observation (guided by checklist)
Session 9	**Report writing** - Hands-on learning of filling in the monitoring report	Findings and observations of study site and study documents; notes and meetings with study team	1. Filling in report based on findings, notes and observations taken during the monitoring visit 2. Discussion of report contents and feedback from the facilitator 3. Group presentation	45	Study documents / Monitoring report forms / Monitoring visit notes	completeness and correctness of monitoring reports following clinical monitor SOPs
Module 5 - Research methodology						
Session 10	Recognize the different types of research designs and objectives of each method in the context of epidemiology research, social & behavioral research, and product development	Common research designs - Epidemiology studies - Social & behavioral studies - Phases of product development and objective of each phase including post-surveillance - Study population, criteria for selection and sample sizes - Stakeholders in different phases of product development	Interactive Power Point presentation	120	ppt as handouts	session 22b

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Module 6 - Study Document management						
Session 11	- Recognize the importance of trial document management - Define and list the essential trial documents - Follow good research practices in assisting the investigator maintain the investigator's file and manage trial documents	- Protocol development and document compatibility (protocol, patient information sheet and CRF) - Purpose of trial master file - List of essential trial documents and purpose - Maintaining trial master file - Maintaining confidentiality - Data and document security - Document archiving rules	Interactive Power Point presentation	45	ppt as handouts / Materials for field practicum	session 22b
Module 7 - Overview of data management and data handling procedures						
Session 12a	Recognize the implication of effective trial document control and quality data on data	- Overview of data management - Generating and resolving data management	Interactive Power Point presentation	60	ppt as handouts	session 22b
Session 12b	- Recognize the importance of quality data management - Define case report forms, source data and source documents and recognize their differences - Follow good research practices in data handling - Know the importance of maintaining CRF and other forms up-to-date and complete	- Source data and source documents - CRF - Source data verification - Corrections to source documents and CRF - HSRI SOP related to Source Data Verification	Interactive Power Point presentation / Field practicum for monitors' course	60	ppt as handouts / Documents for field practicum	session 22b
Module 8 - Informed consent process						
Session 13	- Be acquainted with the informed consent process - Identify the ethical principles that guide the informed consent process - Recognize the documentation of the process	- Process of obtaining informed consent across age groups and cultures - Elements of informed consent - Assessing participant informed consent and their comprehension of information for consent	Interactive Power Point presentation / Review of actual informed consent documents	105	ppt as handouts / Sample information sheet and accompanying written informed consent form	session 22b
Module 9 - Investigational Product Management						
Session 14	- Define an investigational product - Be familiar with requirements for manufacturing, packaging, labeling and coding of investigational product - Be able to trace product receipt, storage, administration and return	- Definition of an investigational product - Labeling in open vs. blinded study - Ensuring adequate supply of investigational product - Product storage requirements - Product accountability and inventory	Interactive Power Point presentation	120	ppt as handouts / documents for field practicum	session 22b
Module 10 - Safety Management						

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Session 15	- Review the stakeholders roles and responsibilities in safety management - Be familiar with good case management, - Define and recognize an adverse event, adverse drug reaction, serious adverse event, unexpected serious adverse drug reaction - Get familiar with the severity grading and causality assessment - Define good reporting practices	- Requirements in terms of safety management for clinical trials - Seriousness vs severity - AE, ADR, SAE, SUSAR and reporting of these events - Safety data reporting during trial implementation and overview of the pharmacovigilance system - Emergency unblinding procedures	Interactive Power Point presentation / Take home quiz given beforehand; results discussed during the lecture	45	ppt as handouts / Take home quiz	session 22b
Mudule 11 - Good Clinical Laboratory Practice						
Session 16	- Be aware of the different areas in laboratory practices: pre-analytical, analytical and post-analytical - Recognize the application of GCP principles to practices in these areas - Define the key areas in assessing a laboratory for GCLP	- Definition, key principles, guidelines - Requirements: personnel, facilities, equipment, supplies and reagents, specimen management, specimen analysis, documentation, QC/QA	Interactive Power Point presentation / Field practicum	120	ppt as handouts / documents for field practicum	session 22b
Module 12 - Quality Management						
Session 17	- Define and recognize the quality systems in health and clinical studies - Apply the quality systems in the studies	- Concepts in quality management systems and their application in a clinical trial –SOPs, monitoring and audit - Audit vs. inspection - Preparing for audits - Most common audit findings - SOP: definition, applicability, design, control	Interactive Power Point presentation	60	ppt as handouts	session 22b and exercise session 18
Session 18	Exercise - Evaluate the potential risk to participants and develop methods/procedures to minimize those risks - Identify systems that enable application of good clinical research practices - Recognize the value of team work among stakeholders in a clinical research - Know the value of standardized procedures	- Identification of ethical justification and scientific validity, GCP issues (i.e., patient care and safety, and data quality) - Measures to minimize participant risk, ensure data quality and obtain study objectives following good research practices	Practical exercise through group activity	45	Documents of a study that has ended / Documents distributed day before	group presentation and discussion
Session 19	SOP writing workshop - Hands-on experience in constructing - Develop draft SOPs for study and site-specific procedures	Application of Sessions 17 and 18	Group work – list the necessary of SOPs and draft the SOPs		Documents on Session 18	group presentation and discussion
Module 13 - Quality of Monitoring						

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Session 20a	Risk-based monitoring - Define risk at each monitoring activities - Use monitoring score calculator - Determine risk categories - Determine monitoring strategies	1. Introduction to risk-based monitoring 2. Risk-based monitoring procedures 3. Risk-based monitoring component - Monitoring score - Decision tree for determining risk categories - Monitoring strategies	Interactive Power Point presentation	60	ppt as handouts / SCTO Plateforms Guidelines for risk-based monitoring V 3.0	session 22b and exercise session 21
Session 20b	Monitoring of non-interventional human research	- Risk consideration - Planning of monitoring procedures - Monitoring procedures	Interactive Power Point presentation	60	ppt as handouts	session 22b and exercise session 21
Session 21	Exercise on risk-based monitoring		Practical exercise	90		
Module 14 - Quiz and course evaluation						
Session 22a	**Recap session**			30		
Session 22b	**Test** - Assess participants' comprehension of the principles of good clinical and their application in clinical studies - Gauge participants' knowledge of clinical studies management according to GCP - Measure participants' pragmatic application of GCP principles in given clinical trial situations	Multiple choice questions that cover above topics	50-question test	60	Questionnaire	80% passing score
Session 22c	**Course evaluation** - Feedback from the participants for future course improvement			30	Evaluation form	