Name:

Enrolment No:

UPES

End Semester Examination, May 2024

Course: Clinical Monitoring **Semester: VI**

Program: BSc Clinical Research **Duration: 3 Hours**

Course Code: HSCR3006 **Max. Marks: 100**

Instructions: Attempt all the Sections

S. No.	Section A **Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)**	Marks	COs
Q 1	What is the primary purpose of monitoring in clinical trials? a) To assign blame b) To ensure compliance with regulations and standards c) To micromanage team members d) To increase workload	**1.5**	**CO1**
Q 2	What is the primary difference between on-site monitoring and centralized monitoring? a) On-site monitoring involves monitoring activities conducted remotely, while centralized monitoring requires physical presence at the study site. b) On-site monitoring focuses on data quality, while centralized monitoring focuses on study protocol adherence. c) On-site monitoring requires less resources compared to centralized monitoring. d) Centralized monitoring is conducted exclusively by the FDA, while on-site monitoring is conducted by sponsors.	**1.5**	**CO2**
Q 3	What role does technology play in alternative monitoring techniques? a) It hinders monitoring efforts by introducing complexity b) It facilitates remote access to study data and real-time monitoring c) It restricts access to study data and records d) It eliminates the need for monitoring altogether	**1.5**	**CO3**
Q 4	How would you describe the monitoring approaches outlined in a monitoring plan? a) They focus solely on remote data monitoring b) They overlook critical data and processes	**1.5**	**CO4**

	c) They detail the methods and frequency of monitoring activities, including on-site visits, centralized review, and remote data monitoring d) They avoid any mention of monitoring activities		
Q 5	In risk-based monitoring, what guides the allocation of monitoring resources? a) Personal preferences of clinical trial sponsors b) The number of monitoring visits previously conducted c) The identified risks associated with trial activities and data d) Ignoring any potential risks	**1.5**	**CO5**
Q 6	What is the purpose of communicating monitoring results in clinical research? a) To withhold information from stakeholders b) To ensure transparency and accountability c) To increase the workload for monitoring teams d) To delay the completion of the monitoring process	**1.5**	**CO1**
Q 7	Which aspect of the protocol is crucial for ensuring the safety of trial participants? a) Statistical analysis plan b) Study objectives c) Inclusion and exclusion criteria d) Marketing strategy	**1.5**	**CO2**
Q 8	How does Electronic Data Capture (EDC) contribute to data quality in clinical trials? a) By increasing manual data entry errors b) By facilitating real-time data validation and review c) By delaying data processing times d) By limiting access controls to authorized personnel only	**1.5**	**CO3**
Q 9	In clinical research monitoring, what role does risk assessment play? a) It helps to increase the complexity of monitoring plans b) It identifies potential risks to data quality and patient safety, guiding monitoring strategies c) It ensures that all monitoring activities are conducted onsite d) It limits the need for monitoring altogether	**1.5**	**CO4**
Q 10	Which of the following is an important qualification for a monitor? a) Extensive experience in a completely unrelated field b) Strong interpersonal skills and ability to communicate effectively c) Limited knowledge about the project area d) A lack of attention to detail	**1.5**	**CO5**
Q 11	Who is responsible for developing the protocol of a clinical trial? a) Regulatory Authority b) Clinical Investigator c) Contract Research Organization (CRO) d) Study Sponsor	**1.5**	**CO1**

Q 12	Which of the following is a primary focus of reviewing the site's process, procedure, and records during monitoring? a) Identifying ways to bypass study protocols b) Ensuring that study staff adhere strictly to monitoring guidelines c) Verifying the accuracy and completeness of study data and documentation d) Ignoring any discrepancies to expedite the study process	**1.5**	**CO2**
Q 13	Which regulatory bodies typically oversee compliance with EDC system requirements? a) International Space Station (ISS) b) Food and Drug Administration (FDA) and European Medicines Agency (EMA) c) World Health Organization (WHO) d) Federal Aviation Administration (FAA)	**1.5**	**CO3**
Q 14	Clinical Investigator Training is essential for: a) Ensuring compliance with regulatory requirements and study protocols b) Identifying potential market competitors c) Designing promotional materials for the investigational product d) Scheduling patient appointments	**1.5**	**CO4**
Q 15	What is the primary objective of risk-based monitoring (RBM) according to FDA guidance? a) To increase workload for clinical trial teams b) To reduce the frequency of monitoring visits c) To focus monitoring efforts on areas most likely to impact data integrity and patient safety d) To eliminate all monitoring activities	**1.5**	**CO5**
Q 16	When should amendments to a monitoring plan be made? a) Only at the end of a clinical trial b) Whenever the monitoring team feels like it c) In response to changes in study protocol, regulatory requirements, or emerging risks d) Never, as amendments might complicate the monitoring process	**1.5**	**CO1**
Q 17	How should monitors be selected for a project? a) Randomly without any consideration for qualifications b) Based on their popularity within the team c) Through a thoughtful process considering relevant expertise and experience d) Only through personal connections without assessing their skills	**1.5**	**CO2**
Q 18	What role does validation play in ensuring the reliability of data captured by EDC systems? a) Validation is not necessary for EDC systems b) Validation ensures that all data entries are manually checked	**1.5**	**CO3**

	c) Validation verifies the accuracy and consistency of data entered into the system d) Validation guarantees that data cannot be accessed or modified		
Q 19	According to FDA guidance, what should be the primary focus of monitoring activities? a) Documenting every aspect of the clinical trial process b) Conducting monitoring visits at the same frequency for all sites c) Ensuring adherence to a rigid monitoring plan d) Identifying and mitigating risks to data integrity and patient safety	**1.5**	**CO4**
Q 20	The extent and nature of clinical monitoring involve: a) Focusing solely on financial aspects b) Limiting monitoring to once a year c) Adapting monitoring activities to project needs and objectives d) Ignoring any deviations from the project plan	**1.5**	**CO5**
Section B (4Qx5M=20 Marks)			
Q 1	Describe the key features and functionalities of Electronic Data Capture (EDC) software.	**5**	**CO3**
Q 2	Describe the essential elements that should be included in a CRF.	**5**	**CO3**
Q 3	Critically analyze the role of technology in facilitating monitoring activities in clinical trials.	**5**	**CO3**
Q 4	Compare and contrast centralized monitoring with on-site monitoring in clinical trials.	**5**	**CO3**
Section C (2Qx15M=30 Marks)			
Q 1	Background: A pharmaceutical company is conducting a multicenter clinical trial to evaluate the efficacy and safety of a new drug for treating a rare disease. The trial involves several study sites across different regions. The company has implemented on-site monitoring to ensure compliance with the protocol, data quality, and patient safety. Scenario: During a routine on-site monitoring visit to one of the study sites, the monitor discovers discrepancies between the source documents and the data entered the electronic case report forms (eCRFs). Some patient data appear to be incomplete or inconsistent, raising concerns about data accuracy and integrity. Additionally, the monitor observes deviations from the study protocol in the administration of the investigational drug and documentation practices. A. Develop an action plan and corrective measures to avoid discrepancies and protocol deviations. 5 Marks B. Mention the role of monitor in developing action plan to avoid discrepancies. 5 marks	**15**	**CO5**

	C. Prepare a monitoring plan for this case study 5 marks		
Q 2	Background: A pharmaceutical company is conducting a Phase III clinical trial to evaluate the efficacy and safety of a potential new treatment for a rare autoimmune disorder. The trial involves multiple study sites across different regions, each enrolling patients according to a strict protocol. Given the complexity of the trial and the need to ensure data quality and protocol compliance, a comprehensive monitoring plan is essential. A. Identify the critical data and process to be monitored. 5 marks B. How is risk assessment performed in this study? 5 marks C. What factors will be considered while developing a monitoring plan for this study? 5 marks	**15**	**CO4**
Section D **(2Qx10M=20 Marks)**			
Q 1	Discuss the communication of monitoring results, management of non-compliance, ensuring quality monitoring, and monitoring plan amendments in clinical trials.	**10**	**CO1**
Q 2	Explain the interplay between protocol and case report design with examples.	**10**	**CO2**