


Format of Question paper-02

Name:			
Enrolment No:			
UPES End Semester Examination, May 2023			
Course: Clinical Monitoring			
Semester : 6			
Program: B.Sc. (Clinical Research)			
Duration : 3 Hours			
Course Code: HSCR3006		Max. Marks: 100	
Instructions:			
S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
Q 1	What is source data verification?	1.5	CO1
Q 2	Who are Monitors?	1.5	CO1
Q 3	What is M&E?	1.5	CO1
Q 4	What are current monitoring practices and FDA guidance?	1.5	CO1
Q 5	What is Risk-Based Monitoring?	1.5	CO2
Q 6	Difference between On-Site and Centralized Monitoring.	1.5	CO2
Q 7	What are current monitoring practices.	1.5	CO2
Q 8	What is the difference between monitoring and evaluation?	1.5	CO2
Q 9	What are the six main components of a project M&E system?	1.5	CO3
Q 10	What are the key design principles for project monitoring and evaluation?	1.5	CO3
Q 11	What is the difference between project design and evaluation criteria?	1.5	CO3
Q 12	What is the relation among temporal association methods for data corrections. eCRF, electronic case report form; SDV, source data verification.	1.5	CO3
Q 13	What is a Protocol and how to execute one?	1.5	CO4
Q 14	How to review a protocol?	1.5	CO4
Q 15	What are the regulatory requirements under ED?	1.5	CO4
Q 16	What are “Data Quality Features” in ED?	1.5	CO4

Q 17	What are Clinical Investigation and Site Selection and Initiation?	1.5	CO5
Q 18	What are additional strategies to ensure study quality?	1.5	CO5
Q 19	What is Document Monitoring Activities.	1.5	CO5
Q 20	What do you understand by Clinical Investigator Training and Communication?	1.5	CO5
Section B (4Qx5M=20 Marks)			
Q 1	What are the limits of project management?	5	CO1
Q 2	What are the challenges of outcome and impact monitoring and evaluation?	5	CO2
Q 3	Describe in detail the various aspects of writing a protocol.	5	CO4
Q 4	Explain: Electronic Data Capture (EDC) System.	5	CO5
Section C (2Qx15M=30 Marks)			
Q 1	Explain Results-based monitoring and evaluation.	15	CO3
Q 2	What is delegation of monitoring responsibilities of a CRO	15	CO4
Section D (2Qx10M=20 Marks)			
Q 1	What are the Criteria for selection of indicators?	10	CO2
Q 2	Explain data collection mechanisms capable of recording progress over time, including baselines and a means to compare progress and achievements against targets.	10	CO5