Name:

Enrolment No:

UPES

End Semester Examination, May 2024

Course: Clinical Data Management

Semester: 6th

Program: Integrated (B.Sc.) - (M.Sc.) Clinical Research

Course Code: HSCR3001 **Time: 03 hrs.**

Max. Marks: 100

Instructions:

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
Q 1	What is the importance of the Case Report Form (CRF) in clinical trials?	1.5	CO1
Q 2	Write the key features of the Clinical Data Management System (CDMS).	1.5	CO1
Q 3	What is the importance of Audit Trails in Clinical Data Management?	1.5	CO1
Q 4	Write the purpose of Randomization in Clinical Trial Design.	1.5	CO2
Q 5	What is the importance of Dose-Finding Studies?	1.5	CO2
Q 6	Patient Diaries do not rely on patient diligence and honesty. (True / False)	1.5	CO1
Q 7	The Electronic Data Collection (EDC) is a real-time data entry and monitoring. (True / False)	1.5	CO1
Q 8	The pre-protocol planning of Clinical Trials does not outline the study design, methods, and statistical considerations. (True / False)	1.5	CO1
Q 9	What is the use of Futility Interim analysis?	1.5	CO2
Q 10	What is Current Procedural Terminology (CPT)?	1.5	CO2
Q 11	How many primary coding systems are used in medical coding?	1.5	CO1
Q 12	What is Data Reconciliation?	1.5	CO1
Q 13	What is the importance of the Clinical Data Interchange Standards Consortium (CDISC)?	1.5	CO2
Q 14	What is data validation in clinical trial data?	1.5	CO1
Q 15	How to measure quality control in data?	1.5	CO2

Q 16	What is the role of a Data Manager?	**1.5**	**CO1**
Q 17	Define Quality Management System (QMS).	**1.5**	**CO1**
Q 18	What is the importance of Data Standardization?	**1.5**	**CO2**
Q 19	What is Adverse Event Reporting?	**1.5**	**CO1**
Q 20	What is the use of Trial Master File (TMF)?	**1.5**	**CO1**
Section B (4Qx5M=20 Marks)			
Q 21	What are the key steps of the medical coding process?	**5**	**CO2**
Q 22	What are Equivalence and Non-Inferiority Trials?	**5**	**CO1**
Q 23	Write the fundamentals of Clinical Trial Design.	**5**	**CO1**
Q 24	Explain the identifying and managing discrepancies of data management.	**5**	**CO2**
Section C (2Qx15M=30 Marks)			
Q 25	Describe the steps and overview process of managing Laboratory Data.	**15**	**CO3**
Q 26	What are the key standards that are widely used in clinical data management?	**15**	**CO2**
Section D (2Qx10M=20 Marks)			
Q 27	Describe the Electronic Data Capture (EDC) steps of modern clinical trials.	**10**	**CO3**
Q 28	Explain the collection of adverse events data typically occurs in a clinical trial.	**10**	**CO2**