


Name:			
Enrolment No:			
UPES End Semester Examination, December 2023			
Course: BSC-Clinical Research Program: Clinical Data Management Course Code: HSCR3001 Instructions: Attempt All Questions.		Semester: Vth Time: 03 hrs. Max. Marks: 100	
S. No.	Section A Short answer questions (20Qx1.5M= 30 Marks)	Marks	COs
Q 1	Define Data.	1.5	CO1
Q 2	What is the role of the database in the clinic?	1.5	CO1
Q 3	Describe the term Clinical Data Management.	1.5	CO2
Q 4	Describe the role of the Data Entry Operator.	1.5	CO2
Q 5	Differentiate between CDMS and CTMS.	1.5	CO2
Q 6	How EDC affects the quality of data.	1.5	CO3
Q 7	Describe the SQL alter command.	1.5	CO1
Q 8	Write short notes on managing laboratory data.	1.5	CO2
Q 9	Discuss any one Data collection approach.	1.5	CO2
Q 10	Describe the Primary Key concept in SQL.	1.5	CO2
Q 11	Phase '0' covers an efficacy study for a small participant size	1.5	CO1
Q 12	Which key provides the relation between tables?	1.5	CO1
Q 13	How many steps does research planning have?	1.5	CO1
Q 14	Security of data related to:	1.5	CO1
Q 15	Define the adverse event.	1.5	CO1
Q 16	AI can improve Clinical Data Management.	1.5	CO3
Q 17	CTMS is used for Clinical Data Management	1.5	CO2
Q 18	Biostatistics studies mainly apply to pre-clinical datasets.	1.5	CO3
Q 19	Missing data in Clinical Trials.	1.5	CO3
Q 20	Cleaning Data in Clinical Trials.	1.5	CO3

Section B (4Qx5M=20 Marks)			
Q 1	Draw Data Management Workflow.	5	CO2
Q 2	Describe the Transcribing Data	5	CO1
Q 3	What is the role of the Data Manager in Clinical Data Management?	5	CO1
Q 4	Discuss Data Management Plan.	5	CO2
Section C (2Qx15M=30 Marks)			
Q 1	Write down the SQL query for extracting the following data from the table: i. Find the details of the patient's age is greater than 45. ii. Find the details of the patients whose city is Dehradun or the BP of a patient greater than 140.	15	CO3
Q 2	Describe the concept of Adaptive design techniques with their advantages and concerns.	15	CO2
Section D (2Qx10M=20 Marks)			
Q 1	Create a table in SQL for the patient that contains information: i. Patient ID, Patient name, Patient City, Patient Age, Patient Bp, Patient doctor name. ii. Delete a record from the patient table whose ID is 6. iii. Add the primary key using the alter table command. iv. Set patient age =30 whose city is Dehradun	10	CO3
Q 2	Describe the Clinical Trail Management System in detail	10	CO1