

Name:	
Enrolment No:	

UPES	
End Semester Examination, December 2023	
Course: BSC-MSC Integrated Clinical Research Program: Data Management Technologies Course Code: HSCR3020P	Semester: Vth Time: 03 hrs. Max. Marks: 100
Instructions: Attempt All Questions.	

S. No.	Section A Short answer questions (20Qx1.5M= 30 Marks)	Marks	COs
Q 1	Data Management role:	1.5	CO1
Q 2	EDC is used to capture data in the form of:	1.5	CO1
Q 3	Why cleaning of data is essential?	1.5	CO2
Q 4	Data Validation is essential in clinical trials.	1.5	CO2
Q 5	Transferring data is related to handling:	1.5	CO2
Q 6	Types of data in a clinical trial:	1.5	CO3
Q 7	SQL Foreign Key use in tables.	1.5	CO1
Q 8	CSV related to Data Management.	1.5	CO2
Q 9	Data collection effective way to store:	1.5	CO2
Q 10	Alter command in SQL used to:	1.5	CO2
Q 11	Proc Step in SAS.	1.5	CO1
Q 12	\$ keyword in SAS.	1.5	CO1
Q 13	ANOVA stands for.	1.5	CO1
Q 14	Histogram of data referred as:	1.5	CO1
Q 15	Describe the adverse event.	1.5	CO1
Q 16	An effective way to analyze the Data.	1.5	CO3
Q 17	The basic syntax for calculating arithmetic mean in SAS is	1.5	CO2
Q 18	Sorting the data which keywords use in SQL.	1.5	CO3
Q 19	SDLC stands for:	1.5	CO3
Q 20	User Acceptance test related to:	1.5	CO3

Section B (4Qx5M=20 Marks)			
Q 1	Discuss Research Planning Steps.	5	CO2
Q 2	How will you manage the Lab Data?	5	CO2
Q 3	How does Computer System Validation Affect the Clinical Trials?	5	CO1
Q 4	Describe each step of SDLC in the Clinical Trail.		
Section C (2Qx15M=30 Marks)			
Q 1	Discuss the components of SAS in CDM.	15	CO3
Q 2	An investigator wants to estimate the mean birth weight of infants born full term (approximately 40 weeks gestation) to mothers who are 19 years of age and under. The mean birth weight of infants born full-term to mothers 20 years of age and older is 3,510 grams with a standard deviation of 385 grams. How many women 19 years of age and under must be enrolled in the study to ensure that a 95% confidence interval estimate of the mean birth weight of their infants has a margin of error not exceeding 100 grams?	15	CO2
Section D (2Qx10M=20 Marks)			
Q 1	<ul style="list-style-type: none"> i. Define Group by Keyword in SQL. ii. Define order by keyword in SQL. iii. What is the use of Alter and update keywords in SQL? iv. What is the use of Primary Key in SQL? 	10	CO3
Q 2	Elaborate about the Clinical Research Tools.	10	CO1