Name:

Enrolment No:

UPES

End Semester Examination, May 2024

Course: Trial Management **Semester: IV**

Program: B.Sc. (Clinical Research) **Time : 03 hrs.**

Course Code: HSCC2024 **Max. Marks: 100**

Instructions: Attempt all the questions

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
1.	Sponsor in a clinical trial is responsible for _____.	1.5	CO1
2.	NDA application is filed _____. a) before clinical trial b) after clinical trial c) before preclinical trial d) after post-marketing	1.5	CO1
3.	List the differences between single and multiple ascending dose.	1.5	CO1
4.	The _____is a critical activity completed by the sponsor prior to the start of a study.	1.5	CO1
5.	Define transgenic model.	1.5	CO2
6.	List the differences between phase I, and II clinical trials.	1.5	CO2
7.	State 3R with respect to ethics of animal research.	1.5	CO2
8.	Define primary and secondary data.	1.5	CO2
9	List essential features of research data management.	1.5	CO3
10.	Cross-sectional study is conducted over a long time period. State whether statement is a) True or b) False	1.5	CO3
11.	Which of the following personnels are not included in a site-initiation visit? a) Sponsor b) Investigator c) Monitor d) Data manager	1.5	CO3
12.	Define sub-investigator and co-investigator.	1.5	CO3
13.	List the common responsibilities of sponsor and investigator.	1.5	CO4
14.	State features of good research data.	1.5	CO4
15.	State the first step in patient recruitment.	1.5	CO4

16.	Name at least one strategy for patient retention.	1.5	CO4
17.	Mention one development strategy for emerging market.	1.5	CO5
18.	State significance of clinical data management.	1.5	CO5
19.	Define Cohort study.	1.5	CO5
20.	Name a non-rodent species used in preclinical studies.	1.5	CO5
Section B (4Qx5M=20 Marks)			
Q	**Attempt all the questions**		
1.	Describe objectives, advantages, and limitations of phase 0.	5	CO1
2.	Differentiate between human and animal testing model.	5	CO2
3.	Discuss the barriers of subject retention and recruitment in clinical research.	5	CO3
4.	Describe the evolutionary history of ethical research.	5	CO4
Section C (2Qx15M=30 Marks)			
Q	**Attempt all the questions (Case studies)**		
1.	Design a case study depicting the statement "BIAS IS EVERYWHERE".	15	CO2
2.	**Background:** • The prevalence of ovarian cancer has increased in your country over the last 5 years. • You want to examine the association between calcium intake and ovarian cancer risk. • You have limited time and funding to conduct this study. **Questions:** 1. What type of study would you conduct? Justify your answer. 2. Why would you conduct that specific type of study? Justify your answer. 3. What is the measure of association to calculate for this study? Justify your answer.	5+5+5=15	CO5
Section D (2Qx10M=20 Marks)			
1.	Differentiate between rat and mice on basis of size, handling, social behavior, disease targeted.	10	CO3
2.	Explain ethics with respect to governing sponsors, sites, investigative personnel, and other affiliated parties.	10	CO4