Name: Enrolment No:	

UPES

End Semester Examination, December 2024

Course: Medical Writing **Semester: VII**
Program: INT. B.Sc. M.Sc. Clinical Research **Time : 03 hrs.**
Course Code: HSCC8010 **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.	_____ is a document regarding patient voluntariness to participate in a clinical trial. a) Case report form c) Informed consent form b) Investigator's brochure d) Confidentiality agreement	1.5	CO1
3.	List any **THREE** differences between sub-investigator and co-investigator.	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 vetting of advertisements.	1.5	CO2
6.	Write any **THREE** benefits of electronic data capture method.	1.5	CO2
7.	Give **TWO** objectives of SOP.	1.5	CO2
8.	Define primary and secondary data.	1.5	CO2
9	List any **THREE** essential features of research data management.	1.5	CO3
10.	Name any two principles of ethics laid down by ICMR in 2006.	1.5	CO3
11.	CTD is _____.	1.5	CO3
12.	NDA application is filed _____. a) before clinical trial b) after clinical trial c) before preclinical trial d) after post-marketing	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.	The _____ in a clinical trial system is the person who initiates, funds and organizes a clinical trial.	1.5	CO4
16.	The _____ is a critical activity completed by the Sponsor prior to the start of a study.	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.	Choose the appropriate steps involved in site qualification of a clinical trial. a) Agreement with sponsor c) Potential PI feasibility b) Pharmacovigilance d) Monitoring visit	1.5	CO5
20.	Investigational storage facility include all except _____. a) Temperature control c) Humidity control b) Dispensing area d) Instrumentation facility	1.5	CO5
	Section B **(4Qx5M=20 Marks)**		
Q	**Attempt all the questions**		
1.	What are the components of good research data?	5	CO1
2.	Explain privacy and confidentiality considerations in clinical trials.	5	CO2
3.	Discuss the essential features of an effective SOP.	5	CO3
4.	Describe the role of data management in clinical drug trials.	5	CO4
	Section C **(2Qx15M=30 Marks)**		
Q	**Attempt all the questions (Case studies)**		
1.	**Background:** Considering implementing a quality system for practice and to interpret readings. Prepare a SOP for any medical device.	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. Propose the requirements for training the team members in and write a brief advertisement.	15	CO5
	Section D **(2Qx10M=20 Marks)**		
1.	Write a note on essentials for public and professional advertising	10	CO3
2.	Explain ethics with respect to governing sponsors, sites, investigative personnel, and other affiliated parties.	10	CO4