Name: **Enrolment No:**	UPES UNIVERSITY OF TOMORROW

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES
End Semester Examination, May 2023

Course: Clinical Trial Management **Semester: IV**
Program: B.Sc. (Clinical Research) **Time : 03 hrs.**
Course Code: HSCC2024 **Max. Marks: 100**

Instructions: Attempt all the questions

Q.No	**Section A** **Short answer questions/ MCQ/T&F**	**(20Q x1.5M= 30 Marks)**	**COs**
Q	Attempt all the questions		CO
1.	Which of the following step is not a part of site qualification visit? a) Financial matters b) Drug approval b) Adverse effect reporting d) Storage area	1.5	CO1
2.	Who is involved in actually conducting a clinical trial? a) Investigator b) Sponsor b) Study coordinator d) Monitor	1.5	CO1
3.	Pharmacovigilance is a part of a) Phase I b) Phase II c) Phase III d) Phase IV Of clinical trial	1.5	CO2
4.	Patient recruitment process mainly affects a) Cost of the study b) Length of the study c) Both a & b d) None of the above	1.5	CO1
5.	The characteristics of Primary data are all except a) Present data b) Published in journals c) Sophisticated to generate d) Expensive	1.5	CO4
6.	The connecting link between the Sponsor and Investigator is a) Pharmacist b) CRO c) Study coordinator d) Data manager	1.5	CO1
7.	What is the main reason for patient withdrawal from clinical trial?	1.5	CO3

	a) Lack of transport b) Serious side effects c) Improper care and facilities d) All of the above		
8.	The clear association between Preclinical and Clinical trial trial is a) Before approval and post-approval b) Animal and human study c) *In vivo* and *In silico* study d) Both a & b	1.5	CO1
9.	What do you understand by discrepancy management? a) Data manipulation b) Data interpretation c) Data validation d) Data lockup	1.5	CO4
10.	Belmont report principles is about all except a) Beneficence b) Justice c) Respect for person d) Contract	1.5	CO3
11.	Contract Research Organization is about a) Outsourcing in clinical trial b) Regulatory body c) Supervision of clinical trial d) Conducting animal study	1.5	CO1
12.	What is remote monitoring in Clinical trial?	1.5	CO5
13.	What is the significance of Edit checks in data management?	1.5	CO3
14.	Write down the main function of FDA.	1.5	CO2
15.	What's your understanding about NDA?	1.5	CO2
16.	What do you mean by data entry?	1.5	CO4
17.	Why is India considered an Emerging market in Clinical research?	1.5	CO6
18.	What is the need of close-out visit?	1.5	CO1
19.	Declaration of Helsinki statement is about?	1.5	CO3
20.	Provide examples of data sources.	1.5	CO4
	Section B	**(4Qx5M=20 Marks)**	CO
Q	Attempt all the questions		

1.	Write at least five principles of Nuremberg code.	5	CO3
2.	What are eligibility and drivers of patient recruitment?	5	CO1
3.	Write down five points to be noticed during site-feasibility visit.	5	CO1
4.	What are the various sources of Primary and Secondary data.	5	CO4
	Section C	**(2Qx15M=30 Marks)**	
Q	Attempt all the questions (Case studies)		CO
1.	**Background:** Chris was recruited to participate in a clinical trial by his oncologist, Dr. Blair. Chris has cancer, and the traditional treatments have been only intermittently successful. The clinical trial is a randomized, single-blinded, placebo-controlled study of a drug that may be beneficial to patients with the kind of cancer that Chris has. The trial is set to last one year, after which time enough data will have been accumulated to determine the efficacy of the new treatment. After six months in the study, Chris is not experiencing any signs of improvement, and he may in fact be getting worse. Dr. Blair continues to receive reports about the progress of the research subjects enrolled in both the treatment arm and in the placebo arm, and preliminary data seem to suggest that the drug is beneficial. During an examination, Chris asks Dr. Blair if he is in the treatment arm or the placebo arm. Chris requests that if he is in the placebo arm Dr. Blair switch him to the treatment arm, so that he can receive the possible benefits of the new treatment. Dr. Blair knows that Chris is in the placebo arm. **Questions:** 1. What single blind, randomized and placebo-controlled is meant to be here? 2. Is it ethical to keep Chris in the placebo arm and should he be transferred to the treatment arm? 3. What other options could be taken to not violate ethical guidelines?	3*5=15	CO3
2.	**Background:** A 52-year-old patient commenced on allopurinol 300mg for the prevention of another acute attack of gout that recently occurred. The patient is known to have moderate to severe renal impairment, but no liver impairment present. Other concomitant medicines: iron sorbitol • insulin (short and long acting) • calcium carbonate. **Questions:** **1** - The aplastic anaemia and subsequent death are adverse events but are they an ADR?	5*3=15	CO3

	2 - What is the likelihood that aplastic anaemia is associated with allopurinol? a. Probable b. Possible c. Unlikely **3** - Did the patient have any risk factors for prescribing the allopurinol? **4** - Was the dose prescribed by the doctor appropriate for the patients' renal function? **5** - Is aplastic anaemia a possible known side-effect with allopurinol?		
	Section D	**(2Qx10M=20 Marks)**	
Q	Attempt all the questions		CO
1.	Write a detailed note on Data management focusing on various steps.	10	CO4
2.	What are the various aspects and types of Monitoring visit. Explain.	10	CO5