Name: **Enrolment No:**	UPES UNIVERSITY WITH A PURPOSE

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES
End Semester Examination, December 2021

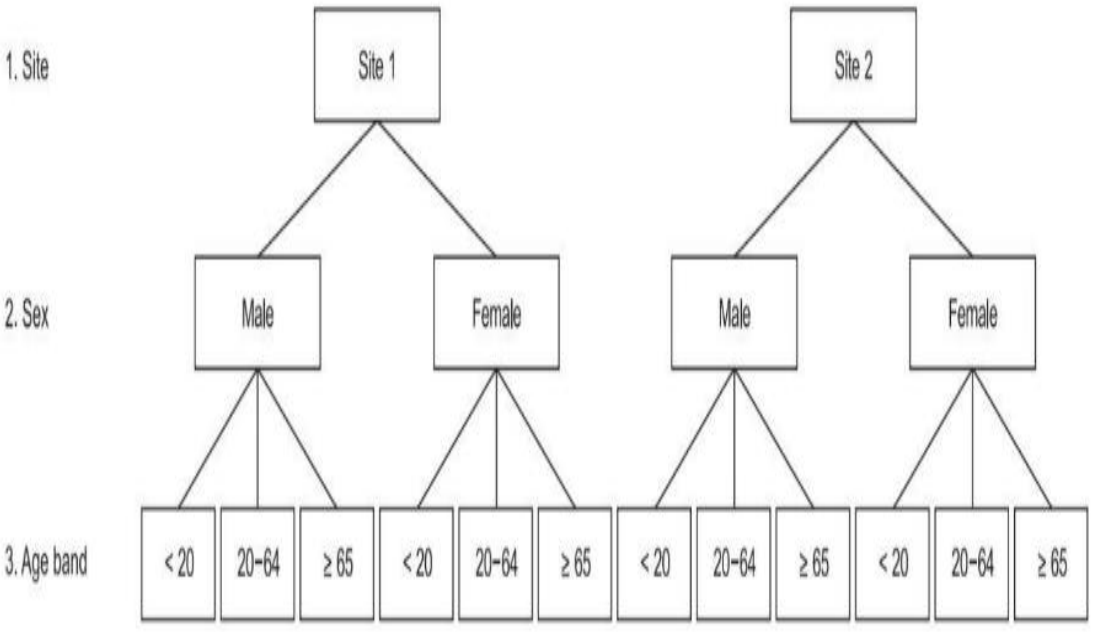
Course: Design of Clinical Trials, Conduct, Audit and Compliance — **Semester:** I
Program: Msc Clinical Research — **Time: 03 hrs.**
Course Code: HSCC7002 — **Max. Marks: 100**

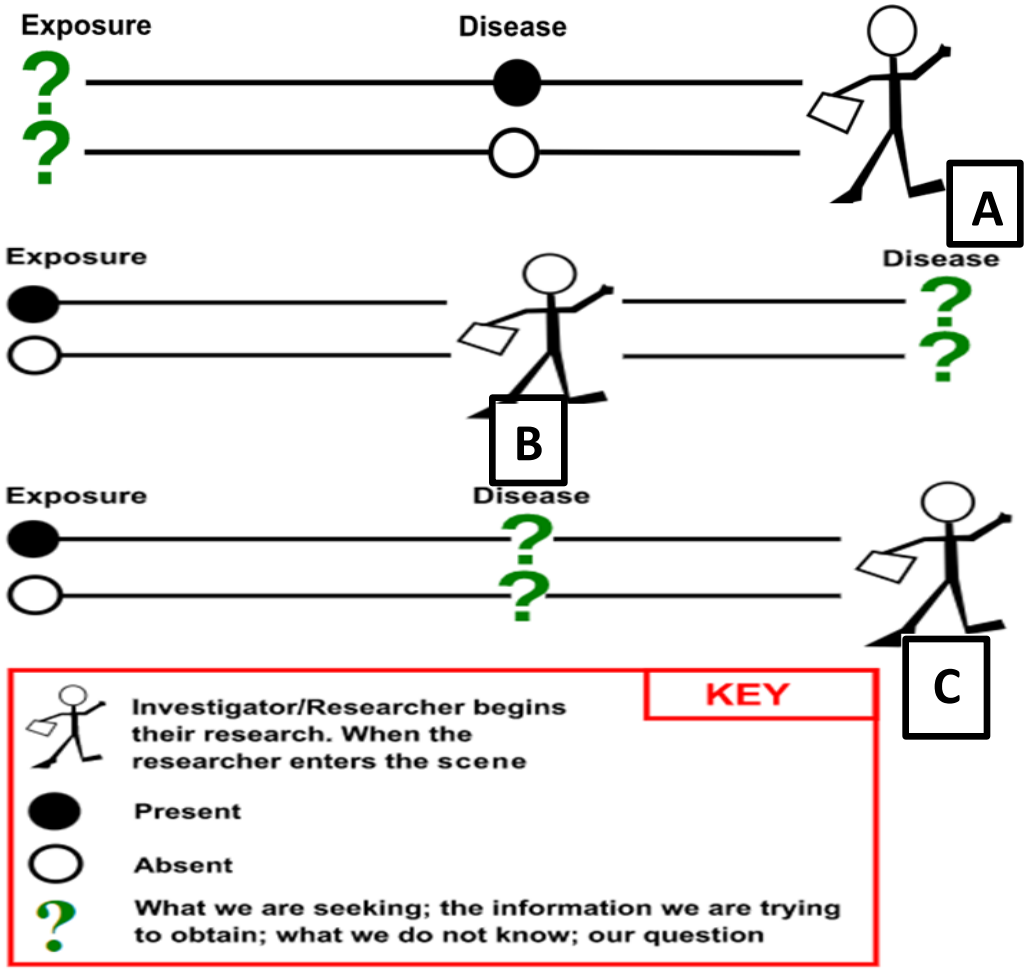
Instructions: Read question carefully.

SECTION A

S. No.	MCQ's /Fill in the blanks/ T&F (1.5 marks each)	**30 Marks**	**CO**
1	The purpose of preclinical testing is: a. To verify that a drug is sufficiently safe and effective to be tested in humans. b. To undergo preliminary testing in healthy humans to monitor the effects of the drug. c. To create a basic outline for the larger scale future tests on a widespread population. d. To develop method of drug analysis	**1.5**	**CO1**
2	Phases of clinical trial involves first time human trial in a small number of patients a. Phase I b. Phase II c. Phase III d. Phase IV	**1.5**	**CO1**
3	How many people will be selected for phase II trial? a . The whole market will be under surveillance b. 500-3000 people c. 100-300 people d. 20-50 people	**1.5**	**CO1**
4	The major purpose of Randomization in clinical trials is to a. Ensure that the groups are comparable on baseline characteristics b. Reduce selection bias in allocation of treatment c. Both A and B d. None of the above	**1.5**	**CO1**
5	The extent to which participants follow the medical advice is known as patients' compliance a. True b. False	**1.5**	**CO5**
6	In which type of study the efficacy of the treatment assesses in a controlled and standardized manner and highly monitored a. Randomized controlled trial b. Case series c. Retrospective study d. Cost-benefit analysis	**1.5**	**CO2**
7	A case-control study is designed to determine whether a particular exposure is associated with a certain outcome or not. a.True b.False	**1.5**	**CO2**

8	Which type of study assesses whether one or more treatments are superior to the others? a. Parallel-design, double-blind trial b. Retrospective cohort study c. Case-control study d. Crossover trial	**1.5**	**CO2**
9	The written details to conduct trails to ensure quality control of trail is known as a. GCP b. SOP c. IEC d. ADR	**1.5**	**CO3**
10	What is informed consent in clinical trial? a. The subjects do not know which study treatment they receive b. Patients injected with placebo and active doses c. Fake treatment d. Signed document of the recruited patient for the clinical trial procedures	**1.5**	**CO3**
11	Case-control studies are always a. Prospective b. Retrospective c. Overmatched d. Multivariate	**1.5**	**CO2**
12	Importance of standard Operating Procedures (SOPs) to a. Manage compliance obligations b. Training stuff c. Both a & b d. None of the above	**1.5**	**CO3**
13	Investigator's brochure updates require a. Before the Clinical Phase of the Trial Commences b. During the Clinical Conduct of the Trial c. After Completion or Termination of the Trial d. All of the above	**1.5**	**CO3**
14	The sponsor in clinical study is a. Country b. Organization c. Society d. Cohort	**1.5**	**CO4**
15	Detection risks, control risks and inherent risks are the common types of audit risks a. True b. False	**1.5**	**CO4**
16	Analytical review, inquiry, observation, inspection, and recalculation are the procedures of ……	**1.5**	**CO4**
17	It is necessary for Clinical Site Audit to a. Educate staff on how to communicate with the auditor b. Ensure personnel understand the protocol and the scientific details of the trial. c. Ensure that all trial documents are well organized and updated d. All of the above	**1.5**	**CO4**
18	The root cause of non-compliance is poor record keeping and lack of training. a.True b.False Justify your answer.	**1.5**	**CO5**

19	The Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP) are responsible for compliance in clinical trial. Justify your answer.	**1.5**	**CO5**
20	Compliance with treatment can be an important determinant of the outcome of clinical trials. a. True b. False Justify your answer.	**1.5**	**CO5**
	SECTION B (5 marks each question)		
Q	Short Answer Type Question (5 marks each) Scan and Upload 4 questions 5 marks. Word limit (100-120)	**20 Marks**	**CO**
1	Describe Clinical Trials Compliance and how to ensure it?	**5 (1+4)**	**CO5**
2	Discuss the principles of clinical audit.	**5**	**CO4**
3	Write a brief note on different types of audit risk and their sources.	**5**	**CO4**
4	For successful clinical research measuring participant compliance is important. Justify the statement.	**5**	**CO5**
	SECTION C 30 marks		
Q	**Two case studies 15 marks each subsections**	**30 Marks**	**CO**
1	(Word limit-250-300) 	**15 (5+10)**	**CO1**

	Q1: Identify the type of clinical trial in the image and explain the ethics related to it. **Q2:** Discuss the different methods of this trial.		
2	Case Study 2 (Word limit- 250-300)  a. Identify the type of clinical study marked as A, B and C. b. Differentiate between B and C c. Develop a study design of the trial with its advantages and disadvantages marked A	**15 (3+3+9)**	**CO2**
	SECTION- D 20 marks		
Q	Long Answer type Questions Scan and Upload (10 marks each) Word limit 200-250	**20 Marks**	**CO**
1	Describe the importance, benefits, and limitations of SOPs	**10**	**CO3**
2	a. Organize all the essential documents required for clinical trial? b. Discuss the plan for an audit	**10 (5+5)**	**CO4**