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

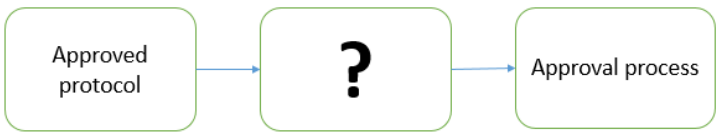
UNIVERSITY OF PETROLEUM AND ENERGY STUDIES
End Semester Examination, May 2021

Course: Perspectives in Clinical Evaluation
Semester: II
Program: M.Sc. (Clinical Research)
Time : 03 hrs.
Course Code: HSCR7009 **Max. Marks: 100**

Instructions: All the sections are compulsory

SECTION A

1. Each Question will carry 1.5 Marks
2. Instruction: Answers all the 20 questions.

S. No.	Type the answer/True or False /MCQ/Fill in the blanks Questions.	**30 Marks**	**CO**
1	1. Which of the following is not a part of clinical trials? a) Biomedical research studies b) Behavioral research studies c) Studies on human subjects d) Study based only on animals	**1.5**	**CO1**
2	How many different types of clinical trials according to the U.S. National Institutes of Health? a) 3 b) 4 c) 5 d) 6	**1.5**	**CO2**
3	Which one of the following describes “double dummy”? 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**
4	What is informed consent in a 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**	**CO4**
5	Which one of the following will perfectly fit on the marked place? 	**1.5**	**CO1**

	a) Investigator selection b) Patient recruitment c) Statistical Analysis d) Data filed and registration		
6	Phase…….trials involve safety surveillance (pharmacovigilance) and ongoing technical support of a drug after it receives permission to be sold.	**1.5**	**CO2**
7	.....finances the study	**1.5**	**CO3**
8	Conflict of interest is a risk factor for scientific misconduct in clinical research studies. (True/False)	**1.5**	**CO4**
9	The Post Marketing trial started after thalidomide tragedy. (True/False)	**1.5**	**CO1**
10	Preclinical Studies are conducted on animals and artificial cells in labs? (True/False)	**1.5**	**CO2**
11	To begin clinical research study, it is mandatory to get approval from? a) Sponsor b) Regulator c) Regulators and ethics committee both d) None	**1.5**	**CO3**
12	Cochrane Back Review Group have been used to evaluate……..	**1.5**	**CO4**
13	What is meant by a "run-in period" for a clinical trial? A. A period before the real trial begins when subjects are screened to ensure that they are committed to the trial and likely to be compliant. B. The period during which the subjects receive their medication packages, in contrast to a "run-out" period, which refers to when they run out of medications. C. The same thing as a "wash-out period." D. When trying to obtain Institutional Review Board (IRB) approve for a study, the investigators sometimes have major differences with the IRB regarding the conduct of the trial. The run-in period is the critical period during which these differences are resolved, usually just before IRB approval is finally obtained.	**1.5**	**CO1**
14	What is meant by "randomization"? (Select the one best answer.) A. Selection of subjects at random. B. Randomization is a method of allocating treatment such that each subject has an equal chance of receiving any of the possible treatments. C. Regression to the mean is a common phenomenon in clinical trials. D. Biases introduce random outcomes	**1.5**	**CO2**
15	Clinical data gathered in the pre-market phase may be too limited to identify rare events or incidents. Post Market Clinical Follow-up is crucial to identify new and unknown risks. (True/ False)	**1.5**	**CO3**
16	The major purposes of random assignment in a clinical trial are: I. Ensure that study subjects are representative of the general population. II. Create treatment groups that are similar with respect to both measured and unmeasured covariates. III. Facilitate double blinding.	**1.5**	**CO4**

	IV. Guard against investigator bias in the allocation of study participants to treatment groups. V. Facilitate the measurement of outcome variables. (a) I and II, (b) II and IV, (c) III and IV, (d) I, III and V		
17	A Clinical Evaluation Report (CER) writer should have good (a) Writing experience, (b) Clinical knowledge, (c) Regulatory Knowledge, (d) All of the above	**1.5**	**CO1**
18	A drug showed the pharmacological action as compared to blank/control, in this case Null hypothesis should be: (a) Accepted, (b) Rejected, (c) Zero, (d) None	**1.5**	**CO2**
19	A new drug molecule is first tested on (a) Healthy people (b) Sick people (c) Animals (d) None of the above	**1.5**	**CO3**
20	A new chemotherapeutic drug molecule is first tested on (a) Phase I, (b) Phase II, (c) Phase III, (d) Phase IV	**1.5**	**CO4**
SECTION B			
Q	Short Answer Type Question (5 marks each) Scan and Upload 4 questions 5 marks each	**20 Marks**	**CO**
1	Write the significance of placebo in clinical trials.	**5**	**CO1**
2	Write steps involved in Post Market Clinical Follow-Up.	**5**	**CO2**
3	Write a short note on general framework for the evaluation of clinical trial quality.	**5**	**CO3**
4	Write a short note on regulatory framework for medical devices.	**5**	**CO4**
SECTION C			
Q	**Two case studies 15 marks each subsection**	**30 Marks**	**CO**
1	A rheumatologist developed a monoclonal Ab that he believes is likely to be effective in RA treatment, and it has successfully moved through Phase 1 and 2 trials. In designing a Phase 3 RCT, comparing to placebo as an add-on therapy for patients already on standard therapy. (i) What are the ethics of clinical research require in this case study? (5) (ii) Explain methodology in this case (5) (iii) What is the role of IRB in this case study? (5)	**15**	**CO1**
2	In a clinical trial: controlled, open-label trial comparing a range of possible treatments in patients who were hospitalized with Covid-19, They randomly assigned patients to receive oral or intravenous dexamethasone (at a dose of 6 mg once daily) for up to 10	**15**	**CO2**

	days or to receive usual care alone. The primary outcome was 28-day survival rate. Here, they report the final results of this assessment. (i) Why is reason of performing open label clinical trial in this research. (5) (ii) What is the outcome measure in this study? (5) (iii) Explain about methodology involved in this clinical trial (5)		
	SECTION- D		
Q	Long Answer type Questions Scan and Upload (not more than 500 words for each question)	**20 Marks**	**CO**
1	(i) Write the steps involved in registry of clinical trial the India? (5) (ii) Explain the biotechnological product and its regulation (5)	**10**	**CO3**
2	(i) Explain the process of filling investigation drug application with flow chart (5) (ii) Explain the Jadad Score Calculation with the help of table chart. (5)	**10**	**CO4**