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

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

Course: **Design of Clinical trial,CA & Compliance** **Semester: 1st**

Program: M.Sc. Clinical Research **Time 03 hrs.**

Course Code: HSCC7002 **Max. Marks: 100**

Instructions:

SECTION A
1. Each Question will carry 5 Marks
2. Instruction: Complete the statement / Select the correct answer(s)

S. No.	Statement of question (Attempt all questions)	**30**	**CO**
Q 1	Mark the following statements True (T) or False (F) Randomized design means a) The subjects do not know which study treatment they receive b) Patients injected with placebo and active doses c) Randomly assigning subjects either for placebo or active dose d) Signed document of the recruited patient for the clinical trial procedures e) Patients injected with placebo and active doses	**5**	**CO1**
Q 2	Which one of the following will perfectly fit on the marked place and why?  a) Investigator selection b) Patient recruitment c) Statistical Analysis d) Data filed and registration	**5**	**CO3**
Q 3	Mark the following statements True (T) or False (F) based on the following research findings. A study was carried out to compare chemotherapy given at home with outpatient treatment for colorectal cancer patients. 42 patients were treated at outpatient clinic and	**5**	**CO2**

	45 at home. Treatment related toxicity was similar in the two groups (difference 7% (95% confidence interval -12% to 26%)), but there were more voluntary withdrawals from treatment in the outpatient group than in the home group (14% v 2%, difference 12% (1% to 24%)). Satisfaction with the communication with the nurse and the doctor were scored on scales from 1 to 100, with higher scores representing greater satisfaction. For communication with the nurse, outpatients' scores had mean (SD) equal to 82 (25) and for home patients these were 100 (0), difference in means (95% CI) -18 (-26 to -9). For communication with the doctor, the corresponding statistics were 70 (26), 70 (22), and 1 (-12 to 14) (The difference is 1 rather than 0 is because of rounding errors.) (*BMJ* 2001;322:826) (a) The trial is double blind. (b) Patients should give written consent before the trial began. (c) There is little or no evidence that voluntary withdrawal differs between home and outpatient treated colorectal cancer patients. (d) All the home treated patients rated their satisfaction with communication with the nurse as 100. (e) We can conclude that, in the population of colorectal cancer patients, there is no difference in satisfaction with communication with the doctor for between home and outpatient treated patients.		
Q 4	Mark the following statements True (T) or False (F) As a rule of thumb about sample size for group based quantitative projects, we should a) Aim to recruit 20 participants per condition of your design b) Aim to recruit 20 participants per member of the group c) Aim to recruit 100 participants per condition of your design d) Aim to recruit 100 participants per member of the group e) Aim to recruit 1000 participants per member of the group	**5**	**CO4**
Q 5	A) Two most important techniques to avoid bias are (a) ……. and (b)…….. B) Bias is a (c)……error contained in the study design, conduct or interpretation of a study. C) Two parallel group design studies are (d)…….and (e)……	**5**	**CO1**

Q 6	Mark the following statements True (T) or False (F) Informed consent in a clinical trial is: 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 procedure e) Patients injected with only active doses.	**5**	**CO2**
	SECTION B **1. Each question will carry 10 marks. Answer all 5 questions.** **2. Instruction: Write short / brief notes**		
	Statement of question	**50**	**CO**
Q 1	What is the composition of Institutional Ethical Committee? How to categorize the clinical trials?	**10**	**CO1**
Q 2	What are the key elements of clinical trial? What is N-of-1 design?	**10**	**CO2**
Q 3	What are the advantages and disadvantages of matched pair parallel design? What does an FDA 483 form mean?	**10**	**CO3**
Q 4	What are the essential documents for audit? What is 3 to 5 minute rule?	**10**	**CO4**
Q 5	What are the different steps involved in FDA inspection process. What are the techniques are used to avoid Bias?	**10**	**CO5**
	SECTION C **1. Each question will carry 20 marks.** **2. Instruction: Write Long Answer.**		
	Statement of question	**20**	**CO**
Q 1	a) What are the risks and benefits of participating in a clinical research study? b) Can I leave a clinical study after it has begun? c) What is an informed consent? (12+3+5) OR a) What is the difference between an observational clinical research study and a clinical trial? b) What is Post marketing surveillance?	**20**	**CO5**