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

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

Course: Quality Control & Quality Assurance in Clinical Trials **Semester : II**
Program: M.Sc. (Clinical Research) **Time : 03 hrs.**
Course Code: HSCR7014P **Max. Marks: 100**

Instructions:

SECTION A

S. No.	MCQs or Fill in the blanks (1 marks each)	30 Marks	CO
1	Periodical operation checks is a part of _____ . A. Quality control B. Quality assurance C. Clinical study report D. Study protocol	1.5	CO1
2	Define quality assurance.	1.5	CO1
3	List the components of clinical trial specific quality assurance audits.	1.5	CO1
4	Write any two current quality challenges encountered in conduct of clinical trial.	1.5	CO1
5	What is the purpose of study site audit during clinical trials? (any three)	1.5	CO2
6	QA auditor is third party personnel who is not directly involved in clinical trials. A. True B. False	1.5	CO2
7	Study site audit is conducted _____ clinical trials. A. Before starting B. throughout C. during first month of starting D. after completion of	1.5	CO2
8	Validation of SAS programs developed for TLG generation is included in _____ _____ during clinical trials. A. Statistical analysis QC B. Installation qualification C. Statistical analysis QA D. Operational qualification	1.5	CO2
9	List any two responsibilities of ethical committees / institutional review board.	1.5	CO3
10	An SAE (Serious Adverse Event) is any untoward medical occurrence that at any dose ___. A. Results in death B. life-threatening C. Results in persistent or significant disability/incapacity D. All of the above	1.5	CO3
11	The person responsible for the conduct of the clinical trial at a trial site is _____ . A. Investigator B. Monitor C. Sponsor D. Clinical research coordinator	1.5	CO3
12	The selection of investigator is a responsibility of _____.	1.5	CO3

	A. Auditor B. Monitor C. Sponsor D. Chairman of IRB		
13	What is table of content in clinical study report?	**1.5**	**CO4**
14	Efficacy evaluation data is included in section _____ of clinical study report. . A. 13 B. 12 C. 11 D. 10	**1.5**	**CO4**
15	Reports of laboratory or vital tests must be included in clinical study report. A. True B. False	**1.5**	**CO4**
16	How adverse events can be classified? (Mention any one criteria)	**1.5**	**CO4**
17	What are the steps of quality by design approach? (any 3)	**1.5**	**CO5**
18	Monitoring involves on-site visits by monitor _____ of a study as part of a quality process. A. Periodically during period B. Before beginning C. After completion D. Any one of the above	**1.5**	**CO5**
19	Significant findings identified as a result of monitoring are escalated for review by_____. A. Quality Assurance (QA) Departments B. Sponsor C. IRB chairman D. Investigator	**1.5**	**CO5**
20	Clinical research quality is designed and embedded in the clinical trial processes well in advance of enrollment of the first patient. A. True B. False	**1.5**	**CO5**
SECTION B			
Q	Short Answer Type Question	**20 Marks**	**CO**
1	Explain quality assurance in clinical trials.	**5**	**CO1**
2	Considering QC monitoring, how will you conduct computer system validation during clinical trials?	**5**	**CO2**
3	What is the significance of Institutional review board in clinical trials.	**5**	**CO3**
4	Summarize the efficacy and safety variables represented in clinical study report (as per ICH E3 guidelines).	**5**	**CO4**
SECTION C 30 marks			
Q	**Two case studies 15 marks each subsections**	**30 Marks**	**CO**
1	Coronavirus disease 2019 is observed with damage to the lung tissues. Thus, a clinical trial is to be planned to administer a Glucocorticoid (assume the drug is "A" at two different doses 6 and 12 mg) for modulation of inflammation-mediated lung injury to the COVID 19 positive patients. A total of 2112 patients were assigned to receive dexamethasone and 4200 to receive usual care. Overall, 475 patients in the group of patients administered with drug A only and 1110 patients in the usual care group died within 28 days after randomization. a) Illustrate the proper format of title page of clinical study report. (5 marks)	**15**	**CO3**

	b) For conducting clinical studies, all the enrolled patients are categorized in different groups. Enlist all those possible groups with their designations, as per your suggestion. (3 marks) c) Which diagnostic tests can be done to confirm inclusion criteria COVID 19 positive patients? (any three) (3 marks) d) Calculate the percentage deaths occurred in each group. (4 marks)		
2	Consider one has to conduct clinical trials of drug "X", which is anti-hyperlipidemic drug. a) Identify the documents need to be ready before starting the trials (Phase I). (4 marks) b) What are possible diagnostic tests that are to be conducted on human trial subjects (any two)? (2 marks) c) Write any four possible inclusion criteria for enrollment of human trial subject. (4 marks) d) Consider you are a QA auditor, what documents will you verify regarding data management and statistical analysis. (5 marks)	**15**	**CO4**
	SECTION- D 20 marks		
Q	Long Answer type Questions	**20 Marks**	**CO**
1	Discuss risk based quality management in clinical trials.	**10**	**CO5**
2	Explain the principles of ICH-GCP.	**10**	**CO3**