Name:

Enrolment No:

UPES

End Semester Examination, December 2023

Course: Design of Clinical Trials, Conduct, Audit and Compliance **Semester : Vth**

Program: Int BMSC Clinical Research **Duration : 3 Hours**

Course Code: HSCR3013 **Max. Marks: 100**

Instructions: All questions are compulsory. Please attempt all.

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
Q 1	Phase 1 of clinical trial is usually done to explore the safety of the treatment. (True/False)	1.5	CO1
Q 2	Microdosing studies are also known as phase 0 studies. (True/False)	1.5	CO1
Q 3	Define Single blind study.	1.5	CO1
Q 4	What is a placebo?	1.5	CO1
Q 5	Define inclusion and exclusion criteria?	1.5	CO2
Q 6	What is case report form?	1.5	CO2
Q 7	Which document is mandatory to enroll subject in clinical research study? a. Protocol b. Case Report Form c. Informed Consent Form d. Investigators Brochure	1.5	CO2
Q 8	_____finances the study. a. Sponsor b. Regulatory body c. Ethics committee d. Investigator	1.5	CO2
Q 9	Conflict of interest is a risk factor for scientific misconduct in clinical research studies. (True/False)	1.5	CO3
Q 10	Adverse Drug Reaction reporting is mandatory in clinical trials. (True/False)	1.5	CO3
Q 11	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	CO3

Q 12	During FDA inspection of the trial regulatory records are reviewed. (True/False)	1.5	CO3
Q 13	According to ICH GCP (International Conference on Harmonization - Good Clinical Practice) guidelines, which document outlines the objective(s), design, methodology, statistical considerations, and organization of a clinical trial? a. Informed Consent Form b. Investigator's Brochure c. Clinical Study Protocol d. Case Report Form	1.5	CO4
Q 14	Although a subject is not obliged to give his/her reason(s) for withdrawing prematurely from a trial, the investigator should make a reasonable effort to ascertain the reason(s), while fully respecting the subject's rights.(True/False)	1.5	CO4
Q 15	Clinical trials should be conducted in accordance with the ethical principles that are consistent with GCP and the applicable regulatory requirement(s), and that have their origin in the Declaration of _____. a. Clinical Research Regulations b. Independence c. Geneva Conference d. Helsinki	1.5	CO4
Q 16	What is SOPs?	1.5	CO4
Q 17	Name the body regulating clinical trials in India.	1.5	CO5
Q 18	A CAPA is a response to findings from an audit or inspection. What does the C stand for? a. Current b. Corrective c. Compliance Coordinated	1.5	CO5
Q 19	Surrogate endpoint is _____ a. A subjective endpoint b. A measurement that is used in place of another measure that is more difficult to assess c. A measurement derived from a combination of assessments A point at which the trial could be stopped for safety reasons	1.5	CO5
Q 20	Write full form of ANOVA	1.5	CO5

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Section B (4Qx5M=20 Marks)			
Q 1	Write the important considerations of clinical trials for CVS disorders.	5	CO 1
Q 2	Discuss in brief about case report form.	5	CO 1
Q 3	Enumerate importance of informed consent form in Clinical trials.	5	CO 2
Q 4	Support the following statement The SOPs are integral part of documentation in clinical trials.	5	CO3
Section C (2Qx15M=30 Marks)			
Q 1	Explain in detail about adaptive design in clinical trials.	15	CO 4
Q 2	Give outline of auditing process in clinical trials and justify the importance of auditing in clinical trials by giving suitable examples.	15	CO 5
Section D (2Qx10M=20 Marks)			
Q 1	Discuss in detail about Patient and Protocol compliance in clinical trials	10	CO 2
Q 2	Classify various clinical trial designs. Explain each design by giving suitable explanation.	10	CO3