Name:

Enrolment No:

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES
End Semester Examination, December 2022

Course: Management of clinical trial **Semester : 3rd**
Program: Int. B.Sc-M.Sc. (Clinical Research) **Duration : 3 Hours**
Course Code: HSCR2015 **Max. Marks: 100**

Instructions: Attempt all

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	Cos
Q 1	Mention the principles of Belmont report.	1.5	CO1
Q 2	What was the purpose of Nuremberg trials?	1.5	CO1
Q 3	Which of the following is NOT associated with Phase 1 clinical trials? (a) ~ 100 participants (b) Patients with target disease (c) Establishment of safety of drug in humans (d) Establishment of normal human dosage	1.5	CO1
Q 4	Explain with example “vulnerable group”.	1.5	CO1
Q 5	What is GCP? Why is it needed?	1.5	CO1
Q 6	State two benefits & two risks of clinical trials.	1.5	CO1
Q 7	Compare the roles and responsibilities of sponsor and clinical trial investigator.	1.5	CO2
Q 8	Data reported on the _____, which are derived from source documents, should be consistent with the source documents or the discrepancies should be explained. A. Statistical Analysis Plan (SAP) B. Case Report Form (CRF) C. Protocol	1.5	CO2
Q 9	Animal studies, clinical trials, bioavailability studies are part of which application process a. IND b. NDA c. ANDA d. BLA	1.5	CO2
Q 10	Explain audit of a trial in reference to source documents.	1.5	CO2
Q 11	Explain exploratory trials.	1.5	CO2
Q 12	What is meant by "randomization" & “run-in-period”?	1.5	CO2
Q 13	True/False, Explain. According to ICH GCP Non-Therapeutic trials may ONLY be conducted with subjects who consent personally and in writing.	1.5	CO3

Q 14	What does the M stand for in CTMS? A. Management B. Medicine C. Material D. Monitoring	1.5	CO3
Q 15	What is the systematised collection of patient and population electronically-stored health information in a digital format? A. EDC B. EHR C. IEM D. Mdoc	1.5	CO3
Q 16	What would you use nQuery for? A. Randomization B. Sample size calculations C. Feasibility D. PK Modelling	1.5	CO3
Q 17	Which UK organisation protects and promotes the interests of patients and the public in health and social care research. A. MHRA B. CPMP C. HRA D. NHS	1.5	CO4
Q 18	What is meant by a blind subject? 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
Q 19	What is meant by "compliance" in a randomized clinical trial? (Select one). A. Flexibility in assignment to treatment groups. B. The degree to which study subjects adhere to an assigned treatment protocol. C. An inter-institutional agreement for a multi-center study. D. Benefits for people who enroll in the study	1.5	CO4
Q 20	Which statement about blinding in an intervention study is NOT correct? (Select one). A. The purpose of blinding is to reduce bias in determining the outcome. B. The purpose of blinding is to reduce confounding. C. In a double blinded study, neither the subject nor the investigators know which treatment the subject is receiving. D. Blinding can be accomplished by using a placebo	1.5	CO4
Section B			

(4Qx5M=20 Marks)			
Q 1	State the need of Non-randomized clinical trials. What controls are used in these trials?	5	CO1
Q 2	Explain in detail what are essential documents as per good documentation practice.	5	CO2
Q 3	State the composition and responsibilities of IRB/IEC.	5	CO3
Q 4	Compare phase 1 and phase 11 clinical trials.	5	CO4
Section C (2Qx15M=30 Marks)			
Q 1	Demonstrate with flowchart site selection process in India. Write about the key requirements in site identification and assessing site feasibility.	15	CO3
Q 2	Discriminate pilot and bridging studies mentioning the ethnic influence, advantages, and disadvantages of each.	15	CO4
Section D (2Qx10M=20 Marks)			
Q 1	Explain the various phases of clinical trials. Brief various types of clinical trials.	10	CO1
Q 2	Write the components of informed consent? Mention in detail the scenarios when informed consent requirement be exempted.	10	CO2