Name:

Enrolment No:

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES

End Semester Examination, December 2022

Course: Clinical Data Management **Semester : V**

Program: B.Sc. Clinical Research **Duration : 3 Hours**

Course Code: HSCR 3001 **Max. Marks : 100**

Instructions:

Give response to sub-questions of Q. (1) as TRUE OR FALSE. Attempt all questions in this paper.

S. No.	Section A Short answer questions (True or False) (20 Q x 1.5 M = 30 Marks)	Marks	COs
Q 1	**1)** Biostatistics studies mainly apply to pre-clinical dataset.	1.5	CO3
	2) Phase '0' covers efficacy study for small participant size.	1.5	CO1
	3) There is limited role of CGO in phase-1 of clinical trial.	1.5	CO4
	4) Issues under GCP, GLP are monitored by IEC.	1.5	CO4
	5) Protocol is required before clinical trial data is collected.	1.5	CO2
	6) e-CRF supports automation based on clinical data.	1.5	CO3
	7) Distributed database with graphs can model clinical data.	1.5	CO2
	8) Clinical data from phase 1 is mostly quantitative.	1.5	CO2
	9) Surrogate baseline is required for safety analysis.	1.5	CO1
	10) Clinical data from phase 2 is mostly qualitative.	1.5	CO2
	11) Baseline refers to start of screening in clinical trial.	1.5	CO1
	12) Schema denotes logical, physical mapping of data entities.	1.5	CO2
	13) Clinical trial in phase 4 must mainly confirm to GLP.	1.5	CO4
	14) SQL programming employs fields that are relational.	1.5	CO2
	15) AI can improve clinical data interpretation.	1.5	CO3
	16) Trees are type of learning structures for clinical dataset.	1.5	CO3
	17) Randomization in clinical trial eliminates selection bias.	1.5	CO1
	18) Masking target intervention and subject identity reduces machine bias.	1.5	CO1
	19) Bigdata is data changing with velocity and volume.	1.5	CO3
	20) CTMS mainly entails automating collection and analytics.	1.5	CO4

Section B **(4 Q x 5 M = 20 Marks)**			
Q 2			
	1) Explain Protocol design in Clinical trial. **2)** Explain the role of ethics in Clinical trial. **3)** What is DBMS, state (at least) four types of DBMS. **4)** What is CRF, give basic points covered in CRF.	**5** **5** **5** **5**	**CO1** **CO4** **CO2** **CO3**
Section C **(2 Q x 15 M = 30 Marks)**			
Q 3	**1)** Consider that clinical trial is performed for diagnostic intervention such as clinical device or apparatus that can measure human physiological or pathological events. Discuss case study relevant to: (**a)** protocol for the trial, (**b)** safety issues, (**c)** efficacy issues, (**d)** cite possible adverse event reporting (if any), (**e)** manufacturing, measurement accuracy and regulatory aspects. **(each sub-question carries 3 marks)**	**15**	**CO4**
	2) Consider that clinical trial is performed for therapeutic intervention (such as drug discovery) meant on some target disorder or disease. Discuss case study relevant to: (**a)** Pre-clinical trial studies and significance, (**b)** Subject enrollment and Informed consent, (**c)** Phase – 3 of clinical trial, (**d)** cite adverse event reporting (if any), (**e)** CRF generation. (**each sub-question carries 3 marks**)	**15**	**CO4**
Section D **(2 Q x 10 M = 20 Marks)**			
Q 4	1) **(a)** Illustrate the seven key application areas of Clinical Trial Systems, **(b)** Elicit various stakeholders and how they contribute in the collection, security and analysis of data for CTMS. **(each sub-question carries 5 marks)**	**10**	**CO4**
	2) **(a)** Define at least four types of bias arising in Clinical trials, **(b)** Reason methods to handle each bias component. **(each sub-question carries 5 marks)**	**10**	**CO2**