Name: **Enrolment No:**	

UPES

End Semester Examination, May 2025

Course: Clinical Data Management — **Semester: 6th**

Program: Int. BMSc. (Clinical Research) — **Duration: 3 Hours**

Course Code: HSCR3001 — **Max. Marks: 100**

Instructions: Read all questions carefully.

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
Q 1	What is the first step in the CDM process? a) Data analysis b) Protocol development c) CRF design d) Regulatory approval	**1.5**	**CO2**
Q 2	What is the primary use of a Case Report Form (CRF)? a) Managing hospital admissions b) Collecting clinical trial data c) Calculating drug dosages d) Marketing trial results	**1.5**	**CO1**
Q 3	A Clinical Research Associate (CRA) primarily: a) Conducts lab experiments b) Monitors clinical trial sites c) Audits insurance companies d) Manages finance reports	**1.5**	**CO2**
Q 4	What does CDISC stand for? a) Clinical Data Interchange Standards Consortium b) Clinical Drug Integration Software Code c) Centralized Data and Information Standards Committee d) Clinical Development Integration Steering Council	**1.5**	**CO1**
Q 5	Patient-reported outcomes are typically collected through: a) Blood tests b) Medical billing c) Surveys and diaries d) Physician prescriptions	**1.5**	**CO2**
Q 6	What is the primary goal of using NCI CDEs in clinical research? a) Speeding up approvals b) Standardizing data elements c) Improving drug cost d) Publishing faster	**1.5**	**CO3**
Q 7	Who maintains the repository of CDEs? a) World Bank b) NIH/NCI	**1.5**	**CO4**

	c) UNESCO d) ICH		
Q 8	UPs differ from AEs because they: a) Are reported casually b) Always result from data entry c) Require prompt reporting to IRB d) Are unrelated to the study	**1.5**	**CO2**
Q 9	ICD codes are primarily used for: a) Conducting surveys b) Medical diagnosis and billing c) Designing CRFs d) Evaluating sponsors	**1.5**	**CO2**
Q 10	What is a data validation check? a) A summary report b) A way to improve color formatting c) A process to ensure data accuracy and completeness d) A method to select volunteers	**1.5**	**CO3**
Q 11	During validation, a "query" is: a) A final report b) A request to resolve a data inconsistency c) An error message d) A clinical assessment	**1.5**	**CO5**
Q 12	What does database "lock" mean in CDM? a) Preventing new trial registrations b) Securing financial records c) No further changes can be made to the trial data d) Suspending patient enrollment	**1.5**	**CO3**
Q 13	Which dictionary is mainly used to code adverse events in clinical trials? a) WHO-DD b) CPT c) MedDRA d) SNOMED	**1.5**	**CO4**
Q 14	Phase I trials mainly test: a) Drug effectiveness b) Marketability c) Safety and dosage d) Drug packaging	**1.5**	**CO5**
Q 15	The phase focused on long-term safety and marketing surveillance is: a) Phase I b) Phase II c) Phase III d) Phase IV	**1.5**	**CO3**
Q 16	Which organization regulates clinical trials in the USA? a) EMA b) WHO c) FDA d) CDSCO	**1.5**	**CO1**
Q 17	ICH stands for: a) International Council for Harmonisation	**1.5**	**CO5**

	b) International Committee of Health c) Indian Clinical Hub d) Integrated Clinical Handbook		
Q 18	DCGI operates under: a) WHO b) US FDA c) Ministry of Health and Family Welfare, India d) ICMR	**1.5**	**CO4**
Q 19	Future CDM professionals are expected to have skills in: a) Traditional typing b) Clinical psychology c) Data science and informatics d) Fashion design	**1.5**	**CO5**
Q 20	What type of database is most frequently used in clinical trials? a) Relational b) Hierarchical c) Object-oriented d) Blockchain	**1.5**	**CO5**
Section B (4Qx5M=20 Marks)			
Q 1	Describe how does Common Data Elements (CDEs) support harmonized data collection in multi-site clinical trials?	**5**	**CO2**
Q 2	Compare unanticipated adverse events (UAEs) with expected ones. How are they addressed and documented?	**3 2**	**CO4**
Q 3	Explain the importance of regulatory audits in clinical trials? Describe two ways audits contribute to trial quality.	**3 2**	**CO5**
Q 4	Describe factorial trial design. Differentiate it from parallel group design in evaluating multiple interventions?	**2 3**	**CO3**
Section C (2Qx15M=30 Marks)			
Q 1	Define Clinical Data Management (CDM). Illustrate its life cycle and significance in clinical study execution.	**7.5 7.5**	**CO3**
Q 2	Explain the advantages of using adaptive designs in clinical trials over traditional fixed designs? Discuss group-sequential methods and interim analyses briefly.	**7.5 7.5**	**CO5**
Section D (2Qx10M=20 Marks)			
Q 1	Describe how different types of data (objective vs. subjective, qualitative vs. quantitative) impact the transparency and reproducibility of clinical research. Use relevant trial examples.	**10**	**CO1**
Q 2	Outline the different clinical trial designs (factorial, and group-randomized), and explain how interim analyses may be used to enhance decision-making.	**10**	**CO4**