Name: **Enrolment No:**	

UPES

End Semester Examination, December 2024

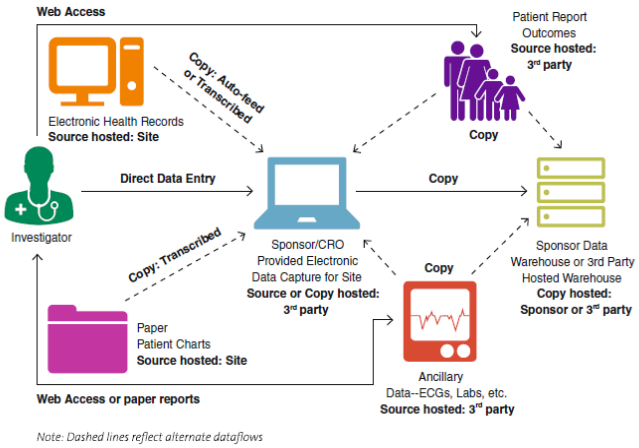
Course: Clinical Data Management — **Semester: 5**

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

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

Instructions:

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
Q 1	Define Clinical Data Management (CDM)	**1.5**	**CO1**
Q 2	Define non-clinical data?	**1.5**	**CO1**
Q 3	List main stages of Clinical Data Management in a clinical trial.	**1.5**	**CO1**
Q 5	Define Case Report Form (CRF)	**1.5**	**CO2**
Q 6	Define Data Validation.	**1.5**	**CO4**
Q 7	Define Data Management Plan (DMP).	**1.5**	**CO1**
Q 8	List the software used for CDM.	**1.5**	**CO3**
Q 9	List the types of data used in CDM.	**1.5**	**CO2**
Q 10	State any **ONE** point of importance of data cleaning in the clinical data management process.	**1.5**	**CO3**
Q 11	Define setup/startup phase of CDM.	**1.5**	**CO1**
Q 12	Define conduct phase of CDM.	**1.5**	**CO1**
Q 13	Define closeout phase of CDM.	**1.5**	**CO1**
Q 14	List any **TWO** benefits of DMP.	**1.5**	**CO2**
Q 15	List any **TWO** types of designs for data capture in CRF.	**1.5**	**CO2**
Q 16	Define adverse events (AE) in CDM.	**1.5**	**CO4**

Q 17	Define reconciliation of AE in CDM.	**1.5**	**CO4**
Q 18	Define AETERM, AESTDTC and AESTTIM.	**1.5**	**CO4**
Q 19	Define ARM, ARMCD, ACTARM and ACTARMCD.	**1.5**	**CO4**
Q 20	Define CDISC.	**1.5**	**CO3**
	Section B **(4Qx5M=20 Marks)**		
Q 1	Define the term clinical. Differentiate between clinical and non-clinical studies.	**1+4**	**CO1**
Q 2	Define sources of data in clinical practices. Referring to the figure below, explain the sources of data in CDM. Source Data Flow  Fig. 11.1 Source dataflow. From Society for Clinical Data Management. eSource Implementation in Clinical Research: A Data Management Perspective: A White Paper [45]	**5**	**CO2**
Q 3	Explain different kinds of CRF design considerations.	**5**	**CO2**
Q 4	Discuss the importance of data management plan and explain its necessity.		**CO2**
	Section C **(2Qx15M=30 Marks)**		
Q 1	You are working as a data manager in a clinical trial and are tasked with creating a demographic table summarizing the baseline characteristics of study participants. • Explain the purpose of a demographic table in Clinical Data Management (CDM). • Discuss the key elements that should be included in a demographic table. • Write and explain the necessary R commands you would use to generate a demographic table from a dataset containing participant demographic information.	**15**	**CO4**
Q2	You are analyzing a clinical dataset that includes patient IDs, age, treatment groups, and lab results. To prepare this data for further	**15**	**CO3**

	analysis, you need to perform data manipulation tasks such as creating new columns and transforming the data.
	• Illustrate the use of the assignment operator (<-), the pipe operator (%>%), and the mutate() function in R for managing and transforming clinical data.
	• Create an example script in R where you:
	  • Assign the dataset to a new variable.
	  • Use the pipe operator to chain commands for readability.
	  • Use the mutate() function to add a new column that categorizes patients based on age (e.g., "Young" for patients under 30, "Middle-aged" for 30-60, and "Senior" for over 60).		

Section D **(2Qx10M=20 Marks)**			
Q 1	Explain in detail Clinical Data Interchange Standards Consortium (CDISC).	**10**	**CO4**
Q2	Explain the importance and key components of a Case Report Form (CRF) in Clinical Data Management. Discuss how CRF design impacts the quality of clinical trial data and describe the best practices for developing an effective CRF.	**10**	