

## M.Sc Sem-3 Examination

302

## Clinical Research

November-2024

Time : 2-30 Hours]

[Max. Marks : 70

**Instructions:**

- Attempt all questions from question.1 to question.4.
- Attempt any fourteen questions in question.5.

**Que. 1 Describe the following :**

- a) Explain in detail Data Management Process. 07
- b) Explain Guideline for CRF designing & filling. 07

OR

**Que. 1 Describe the following:**

- a) Code of Ethics for CDM professionals. 07
- b) Explain Remote Data Entry. 07

**Que. 2 Describe the following:**

- a) Discuss paper based and electronic data capture. 07
- b) Write short Note: Audit Trail. 07

OR

**Que. 2 Describe the following:**

- a) What is data tracking? Data tracking challenges with examples. 07
- b) Describe different methods of Data Transcribing 07

**Que. 3 Describe the following:**

- a) Short Note on various tools use for data coding. 07
- b) Describe in detail Data freezing Process. 07

OR

**Que. 3 Describe the following:**

- a) Explain Data Coding Process. 07
- b) Write a note on Data cleaning and validation. 07

**Que. 4 Describe the following:**

- a) Roles & Responsibilities of Clinical Data Manager. 07
- b) Elaborate Randomization and Blinding Methods. 07

OR

**Que. 4 Describe the following**

- a) Explain in detail about Measures of Central Tendency. 07
- b) Define standard deviation. The marks obtained by 8 students in a test of 100 marks in statistics are as follows: 49, 46, 47, 44, 43, 45, 48, 52. Find the variance and the standard deviation for the data. 07

(P.T.O)

**Module VIII Clinical Data Management & Biostatistics****Que. 5 Answer the following (write any 14 out of 17)****14**

1. Define: Heads up and Heads down data entry
2. Give full form of ANOVA\_\_\_\_\_
3. Define: Verbatim Term
4. Define: SAE Reconciliation
5. With respect to CRF, differentiate between open ended & closed ended questions with example
6. What is a self evident correction? Explain with example
7. What is a soft lock in data locking?
8. Enlist any three different applications of biostatistics
9. Define t-test and Z-test
10. Define null hypothesis.
11. In which condition recoding is required?
12. Give full form of : CDISC
13. Give full form of CFR\_\_\_\_\_
14. Define: Open System
15. Define: Electronic Records
16. The graph of the normal distribution depends upon the standard deviation. True/False. Justify.
17. Query forms are records of patient data just as the CRFs. True /False. Justify