

Instructions:

- Question-1 to Question-4 are compulsory.
- Attempt any fourteen questions in question.5.

Que. 1 Describe the following:

- a) Discuss in detail Audit Trail. 07
- b) Explain Role of Discrepancy Management System in DM. 07

OR

Que. 1 Describe the following:

- a) Salient features of a CDM Professionals. 07
- b) Write a short Note on 21CFR 11. 07

Que. 2 Describe the following:

- a) Explain in brief advantages and disadvantages of paper CRF and EDC. 07
- b) Write in detail data entry in clinical data management. 07

OR

Que. 2 Describe the following:

- a) Write a short note on tracking of CRF pages and corrective step to identify errors. 07
- b) A data management team was audited by the DSMB. You are the member of the DSMB, make a checklist of documents to be audited by the DSMB. 07

Que. 3 Describe the following:

- a) Describe in detail Data Locking Process. 07
- b) Give overview of Data Management Soft-wares and coding dictionaries. 07

OR

Que. 3 Describe the following:

- a) Explain SAE Reconciliation. 07
- b) What is data cleaning? Describe different methods of identifying discrepancies and explain how the discrepancies can be managed and resolved during data cleaning. 07

Que. 4 Describe the following:

- a) Explain Role of Biostatistician in Clinical Research. 07
- b) Write in detail Roles & Responsibility of CDM. 07

OR

Que. 4 Describe the following

- a) Explain Hypothesis testing & statistical terms. 07
- b) Write a short note on Non-parametric test. 07

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Que. 5 Answer the following (write any 14 out of 17)

1. Define: T-test
2. Give full form of SEC _____
3. What is the definition of hybrid system? Give an example
4. Define: Z-test
5. Define: Krushal-Wallis test
6. Define: Edit check and edit check specification
7. Give full form of ICD9CM _____
8. Define p-value.
9. Give full form of : CDISC
10. Enlist any 3 EDC Softwares
11. Define: Open discrepancies.
12. Define: Heads up Entry
13. Give responsibility of QA/QC in data tracking.
14. Define: OCR
15. Give full form of UAT _____
16. The standard error mean (SEM) can be calculated by(Tick any one):
a) $SEM=S.D./\sqrt{N}$ b) $SEM=S.D.2/\sqrt{N}$ c) $SEM=\sqrt{S.D./N2}$ d) $SEM=S.D./\sqrt{N}$
17. EDC systems do lock the database faster than paper based studies. True/false. Justify

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