

Total No. of Questions : 5]

SEAT No. :

PF12125

[Total No. of Pages : 2

[6648]-823

S.Y. M.B.A.

SE PHM-10 : CLINICAL DATA MANAGEMENT

(2024 Pattern) (Semester-IV)

Time : 2½ Hours]

[Max. Marks : 50

Instructions to the candidates:

- 1) *All questions are compulsory.*
- 2) *Figures to the right indicate full marks.*
- 3) *Draw neat diagrams wherever necessary.*
- 4) *Use suitable examples wherever applicable.*

Q1) Answer any Five out of Eight:

[5×2=10]

- a) Define Clinical Trial.
- b) What is Source Data Verification (SDV)?
- c) Define Data Integrity.
- d) What is Medical Coding?
- e) Define Database Lock.
- f) What is Pharmacovigilance?
- g) Define Data Reconciliation.
- h) State any two objectives of Query Resolution.

Q2) Attempt any Two out of Three:

[2×5=10]

- a) Explain the phases of clinical trials and role of Clinical Data Management in each phase.
- b) Discuss the importance of patient confidentiality and data security in clinical research.
- c) Explain the role of coding dictionaries and standardization in Clinical Data Management.

P.T.O.

Q3) Answer 3(a) or 3(b).

[10]

- a) A clinical research organization observed inconsistent adverse event reporting across multiple clinical trial sites. Analyze the causes of inconsistency and suggest suitable measures for improving reporting accuracy and patient safety.

OR

- b) A pharmaceutical company plans to implement a centralized clinical database system. Evaluate the importance of database validation, audit trails, and backup management in ensuring effective clinical data management.

Q4) Answer 4(a) or 4(b).

[10]

- a) Analyze the impact of poor documentation and inadequate audit trail management on regulatory inspections and clinical trial outcomes. Recommend suitable quality assurance measures.

OR

- b) A health care analytics company is integrating Electronic Health Records (EHR) with clinical research systems. Analyze the benefits, operational challenges, and security concerns associated with healthcare data integration.

Q5) Answer 5(a) or 5(b).

[10]

- a) Evaluate the role of digital transformation and automation in improving operational efficiency and data quality in Clinical Data Management.

OR

- b) Design a strategic framework for improving clinical data quality, regulatory compliance, and reporting efficiency in a global clinical research organization.

