Maharshi Karve Stree Shikshan Samstha's

Smt. Hiraben Nanavati Institute of Management & Research for Women

INTERNAL EXAMINATION – Sem II – (Jan- July 2026)

SUBJECT : Clinical Data Management **SUBJECT CODE: PHM 10**

Date: 12-05-2026 **Pattern : 2024**

Duration : 150 min **Max Marks : 50**

Instructions for students :

- *Marks are indicated for each question.*
- *Handwriting should be eligible for evaluation.*
- *Marks will be given for quality, not quantity.*

Q.1] Answer the following questions
(2 Marks Each) (*10 Marks)*

a) Define Clinical Data Management (CDM) and state its importance in clinical research.

b) List any four phases of clinical trials.

c) What is a Case Report Form (CRF)?

d) Name any two regulatory bodies in clinical trials.

e) Match the following:

Column A	Column B
1. GCP	a. Drug safety monitoring
2. Pharmacovigilance	b. Ethical clinical research practices
3. EDC	c. Electronic data collection
4. SOP	d. Standard procedures

Q.2] Attempt any Two (5 Marks Each) *(10 Marks)*

a) Compare Electronic Data Capture (EDC) systems and traditional paper-based data collection.

b) Summarize the lifecycle of clinical data from collection to submission.

c) Contrast Quality Control (QC) and Quality Assurance (QA) in clinical data management.

Q.3] Attempt any One (10 Marks) *(10 Marks)*

a) Explain the steps involved in Clinical Data Management and its role in clinical trials.

b) Demonstrate the components of a Data Management Plan (DMP) and explain how it ensures data quality and integrity.

Q.4] Attempt any One *(10 Marks)*

a) A clinical trial is facing issues related to data inconsistency and missing data. Analyse the problem and suggest data quality control and assurance measures to resolve these issues.
OR
b) Analyse the impact of regulatory requirements (FDA, EMA, ICH, GCP) on clinical data management practices and discuss the role of stakeholders.

Q.5] Answer the following (any one) *(10 Marks)*

a) Develop a Data Management Plan (DMP) for a clinical trial, including CRF design, data collection methods, quality control, and data security measures.
OR
b) Create a project proposal for implementing a new clinical data management strategy, incorporating EDC systems, data privacy, regulatory compliance, and statistical analysis tools (SAS/SPSS).