



School of Digital Health

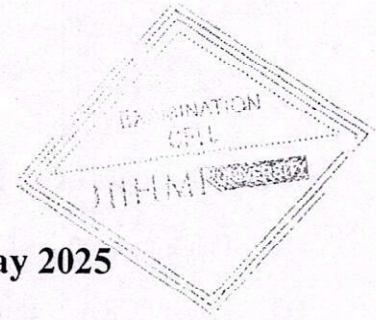
MBA Healthcare Analytics

Batch-01st (2024-2026)

First Year, Term 3, End Term Examinations, May 2025

CC – 616 Clinical Data Management

Enrolment No.:



Time - 3 Hour

Maximum Marks: 50 (Minimum Marks: 20)

Instructions to students:

- This question paper contains 2 printed pages.
- Don't write anything on the Question Paper except writing your Enrolment No.

Part A

(Maximum Marks: 5)

Q1. Choose the correct option for the following questions (1 mark each):

- According to ICH-GCP, who is ultimately responsible for the quality and integrity of trial data?
 - Principal Investigator
 - Sponsor
 - Regulatory Authority
 - Contract Research Organization (CRO)
- Which ICH-GCP principle emphasizes that the benefits of a clinical trial should justify the risks?
 - Principle 1 – Ethical conduct
 - Principle 2 – Risk-benefit assessment
 - Principle 7 – Informed consent
 - Principle 13 – Quality control
- What is the main function of an IRB/IEC (Institutional Review Board/Independent Ethics Committee)?
 - To approve clinical trial budgets
 - To ensure the rights, safety, and well-being of trial participants
 - To conduct statistical analysis of trial data
 - To manufacture investigational drugs
- Which of the following is NOT a key responsibility of a Clinical Research Associate (CRA)?
 - Conducting site monitoring visits
 - Designing the clinical trial protocol
 - Ensuring compliance with ICH-GCP guidelines
 - Verifying source data against case report forms (CRFs)
- What is the primary purpose of a Phase 0 clinical trial?
 - To establish the maximum tolerated dose (MTD)
 - To assess pharmacokinetics and pharmacodynamics with sub-therapeutic doses
 - To compare the new drug with standard treatment
 - To evaluate long-term safety in a large patient population

Part B

(Maximum Marks: 15)

Write Short Notes (Attempt any three – 5 marks each):

- Q2. Phase 0 of Clinical Trial
- Q3. Role of CRA in clinical Research
- Q4. Medical Coding
- Q5. IRB

Part C

(Maximum Marks: 30)

Answer any three of the following questions in detail (10 marks each):

- Q6. Explain ICH-GCP and its 13 principles.
- Q7. Explain the difference between statistical significance and clinical significance in the context of a Clinical Trial.
- Q8. Explain the New drug and clinical trial rules in detail.
- Q9. Explain the structure, responsibility, and process overview of the Clinical Data Management (CDM) team.

