Enrolment No.: .....

IITHMR UNIVERSITY

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

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):

a) According to ICH-GCP, who is ultimately responsible for the quality and integrity of trial data?
a) Principal Investigator
b) Sponsor
c) Regulatory Authority
d) Contract Research Organization (CRO)

b) Which ICH-GCP principle emphasizes that the benefits of a clinical trial should justify the risks?
a) Principle 1 – Ethical conduct
b) Principle 2 – Risk-benefit assessment
c) Principle 7 – Informed consent
d) Principle 13 – Quality control

c) What is the main function of an IRB/IEC (Institutional Review Board/Independent Ethics Committee)?
a) To approve clinical trial budgets
b) To ensure the rights, safety, and well-being of trial participants
c) To conduct statistical analysis of trial data
d) To manufacture investigational drugs

d) Which of the following is NOT a key responsibility of a Clinical Research Associate (CRA)?
a) Conducting site monitoring visits
b) Designing the clinical trial protocol
c) Ensuring compliance with ICH-GCP guidelines
d) Verifying source data against case report forms (CRFs)

e) What is the primary purpose of a Phase 0 clinical trial?
a) To establish the maximum tolerated dose (MTD)
b) To assess pharmacokinetics and pharmacodynamics with sub-therapeutic doses
c) To compare the new drug with standard treatment
d) To evaluate long-term safety in a large patient population

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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.