



**M.TECH DEGREE EXAMINATIONS: DEC 2022**

(Regulation 2018)

Third Semester

**BIOTECHNOLOGY**

P18BTE0006: Clinical Research and Management

**COURSE OUTCOMES**

- CO1:** Understand key areas of drug development, clinical research regulations, trial management
- CO2:** Classify the roles and responsibilities of clinical research professions
- CO3:** Develop skills in clinical research documentation
- CO4:** Understand the general principles on ethical considerations involving human subjects
- CO5:** Identify and classify different types of trial designs
- CO6:** Apply and demonstrate critical analysis skills using tools of CDM

**Time: Three Hours**

**Maximum Marks: 100**

**Answer all the Questions: -**

**PART A (10 x 1 = 10 Marks)**

1. Examine the two statements carefully and select the answer using the codes given CO1 [K<sub>4</sub>]  
below:  
**Assertion (A):** A large scale production of product involves use of bioreactions  
**Reason (R):** Drugs has to undergo through clinical trials before marketing
  - a) If both assertion and reason are true and the reason is the correct explanation of the assertion.
  - b) If both assertion and reason are true but reason is not the correct explanation of the assertion.
  - c) If assertion is true but reason is false
  - d) If both assertion and reason are false
2. Arrange the drug development phases: CO1 [K<sub>2</sub>]
  1. NDA Application
  2. Preclinical research
  3. IND Application
  4. Clinical research
  - a) 2-3-4-1
  - b) 1-3-2-4
  - c) 3-4-2-1
  - d) 4-1-3-2

3. According to the principles of ICH GCP, what is the most important consideration when conducting a clinical trial? CO2 [K<sub>2</sub>]

- a) Data accuracy
- b) Protection of trial subjects
- c) Process adherence
- d) Statistical quality checks

4. Match List II with their respective years (List I): CO1 [K<sub>1</sub>]

List I	List II
A. 1930s	i. Declaration of Human Rights
B. 1948	ii. Food, Drugs, and Cosmetic Act
C. 1964	iii. ICH-GCP guidelines issued
D. 1996	iv. Declaration of Helsinki

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|----|-----|-----|-----|-----|
|    | A   | B   | C   | D   |
| a) | i   | ii  | iii | iv  |
| b) | ii  | i   | iv  | iii |
| c) | ii  | iii | iv  | i   |
| d) | iii | i   | iv  | ii  |

5. Examine the two statements carefully and select the answer using the codes given below: CO3 [K<sub>2</sub>]

**Assertion (A):** All subjects are aware of the clinical trial they are involved in.

**Reason (R):** Informed Consent Form is obtained from every subject.

- a) If both assertion and reason are true and the reason is the correct explanation of the assertion.
- b) If both assertion and reason are true but reason is not the correct explanation of the assertion.
- c) If assertion is true but reason is false.
- d) If both assertion and reason are false.

6. Which of the following reviews prospective studies prior to them beginning, in order to ensure there are no potential legal or ethical violations? CO3 [K<sub>1</sub>]

- a) Institutional Review Board
- b) U.S. Department of Health and Human Services
- c) Internal Review Board
- d) Faculty Review Board

7. Which of the following are not correct on the basis of clinical trials? CO4 [K<sub>2</sub>]

- a) Biomedical research studies
- b) Behavioral research studies
- c) Studies on human subjects
- d) Study based only on animal

8. Given are statements that represent various phase of clinical trials. Identify the trial and sequence the statements based on the trials from phase 1 to phase 4. CO4 [K<sub>3</sub>]

1. The trial is designed to assess the safety (pharmacovigilance), tolerability, pharmacokinetics, and pharmacodynamics of a drug.
2. They are performed on larger groups 20-300 and are designed to assess how

well the drug works, as well as to continue Phase I safety assessments in a larger group of volunteers and patients.

3. The trial involves safety surveillance (pharmacovigilance) and ongoing technical support of a drug after it receives permission to be sold.
4. This phase of the trial depends on the disease and is aimed at being assessment of how effective the drug is, in comparison with current treatment method.

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|------------|------------|
| a) 1-2-3-4 | b) 4-3-2-4 |
| c) 2-3-1-4 | d) 1-2-4-3 |

9. Abbreviate SAE CO5 [K<sub>1</sub>]

- |                            |                            |
|----------------------------|----------------------------|
| a) Safety Advantage Effect | b) Site Acceptance Effect  |
| c) Safety Adverse Effect   | d) Safety Adversity Effect |

10. Examine the two statements carefully and select the answer using the codes given below: CO5 [K<sub>4</sub>]

**Assertion (A):** Clinical trial is performed as per designed protocol.

**Reason (R):** Preclinical studies do not involve humans.

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|--|--|
| a) If both assertion and reason are true and the reason is the correct explanation of the assertion. | b) If both assertion and reason are true but reason is not the correct explanation of the assertion. |
| c) If assertion is true but reason is false.   | d) If both assertion and reason are false.   |

### PART B (10 x 2 = 20 Marks)

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|---|-----------------------|
| 11. What are clinical trials, and why are they important?                                   | CO1 [K <sub>1</sub> ] |
| 12. Define double blind method.   | CO1 [K <sub>1</sub> ] |
| 13. What is a placebo?  | CO2 [K <sub>1</sub> ] |
| 14. List the difference between consent and assent.   | CO2 [K <sub>4</sub> ] |
| 15. Discuss the recent amendments in schedule Y with special reference to ethics committee. | CO3 [K <sub>3</sub> ] |
| 16. Recall the documents for conducting clinical trials                                     | CO3 [K <sub>2</sub> ] |
| 17. Identify the following abbreviations: 1) NDA, 2) FDA 3) EU 4) CDSCO                     | CO4 [K <sub>3</sub> ] |
| 18. Appraise on the functions of EMEA.  | CO4 [K <sub>2</sub> ] |
| 19. Name the steps involved in clinical data analysis                                       | CO6 [K <sub>1</sub> ] |
| 20. How are the BA/BE studies carried out?  | CO5 [K <sub>2</sub> ] |

**PART C (10 x 5 = 50 Marks)**

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|--|-----|-------------------|
| 21. Appraise about informed consent in clinical trials.                                    | CO1 | [K <sub>5</sub> ] |
| 22. Describe the benefits and risks associated when taking part in a clinical trial?       | CO1 | [K <sub>2</sub> ] |
| 23. Evaluate the guidelines for good clinical lab practices.                               | CO2 | [K <sub>5</sub> ] |
| 24. Illustrate with a example the information given in a Investigators brochure.           | CO2 | [K <sub>2</sub> ] |
| 25. Determine the regulatory bodies which are concerned with the clinical research.        | CO3 | [K <sub>5</sub> ] |
| 26. Design a flow chart for the institutional review board with designations.              | CO3 | [K <sub>6</sub> ] |
| 27. Interpret the protocols to be followed during clinical trials.                         | CO4 | [K <sub>2</sub> ] |
| 28. Create an organizational chart for the conducting of clinical trials for vaccine.      | CO4 | [K <sub>6</sub> ] |
| 29. Categorize the steps used for research on CDM.   | CO6 | [K <sub>4</sub> ] |
| 30. Plan a detailed protocol for the carrying out Clinical research and its data analysis. | CO5 | [K <sub>3</sub> ] |

**Answer any TWO Questions**

**PART D (2 x 10 = 20 Marks)**

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|--|-----|-------------------|
| 31. Explain in detail the role and responsibilities of a) investigator b) clinical research associate c) Regulatory authority as per ICH –GCP.   | CO3 | [K <sub>2</sub> ] |
| 32. Imagine a SMO contacts you as a member for volunteering for a clinical trial. Describe the various procedures/ concerns as a volunteer you would raise to participate in the activity. | CO4 | [K <sub>2</sub> ] |
| 33. Survey the various report writing techniques with special mention to transcription and data retention cycle.   | CO5 | [K <sub>4</sub> ] |

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