



15792

**BRAINWARE UNIVERSITY**

Term End Examination 2025-2026
Programme – B.Sc.(MLT)-2022/B.Sc.(MLT)-2023
Course Name – Clinical Research & Toxicology
Course Code - BMLTC503
(Semester V)

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Brainware University
 398, Ramkrishnapur Road, Barasat
 Kolkata, West Bengal-700125

Full Marks : 60**Time : 2:30 Hours**

[The figure in the margin indicates full marks. Candidates are required to give their answers in their own words as far as practicable.]

Group-A

(Multiple Choice Type Question)

1 x 15=15

1. Choose the correct alternative from the following :

- (i) In case of QSEM, identify the correct word for E.
- | | |
|--------------|--------------|
| a) Efficient | b) Efficacy |
| c) Effect | d) Evolution |
- (ii) If the exposure took place in the past and the outcome also occurred in the past the study- select the right term for the corresponding type of study.
- | | |
|------------------------|------------------------------|
| a) Cohort study | b) mixed cohort study design |
| c) retrospective study | d) prospective study |
- (iii) Select the correct law details for the clinical trial documentation purpose.
- | | |
|-------------------------|--------------------------|
| a) GCP E10 Section 9 | b) ICH-GCP E10 Section 9 |
| c) ICH-GCP E6 Section 8 | d) ICH-GCP E10 Section 8 |
- (iv) Which of the following is an example of a medication error?
- | | |
|-----------------------------------|------------------------------|
| a) Administering a drug correctly | b) Misreading a prescription |
| c) A known side effect | d) An allergic reaction |
- (v) What is an example of a noxious response?
- | | |
|---------------------------------------|-------------------------------------|
| a) A headache after taking medication | b) A rash from an allergic reaction |
| c) Drowsiness from an antihistamine | d) Improved symptoms |
- (vi) What is the main purpose of Phase 0 clinical trials?
- | | |
|---------------------------------------|--|
| a) To determine drug effectiveness | b) To streamline the drug approval process |
| c) To test for long-term side effects | d) To evaluate quality of life |
- (vii) Identify the type of study to avoid bias between doctor and patient
- | | |
|-----------------------|------------------------|
| a) Open-label study | b) Double-blind study |
| c) Single-blind study | d) Observational study |
- (viii) What do Phase III trials aim to demonstrate?
- | | |
|--|--|
| a) That the drug is affordable | b) That the treatment is easy to administer |
| c) That the treatment is available worldwide | d) That the new treatment is more effective than standard treatments |
- (ix) Select correct explanation of cohort study
- | | |
|--|--|
| a) A randomized controlled trial | b) An analytical observational study following a group over time |
| c) A study focused on laboratory experiments | d) A qualitative research method |
- (x) identify the primary function of pharmacodynamics
- | | |
|---|--|
| a) To assess drug distribution | b) To study drug interactions |
| c) To analyze how drugs produce their effects | d) To evaluate patient adherence to medication |
- (xi) Identify the typical effect of competitive antagonists
- | | |
|--|---|
| a) They activate the receptor | b) They increase the effect of an agonist |
| c) They block the action of an agonist | d) They have no effect on receptor activity |
- (xii) What does LD50 represent?
- | | |
|--|---|
| a) The lethal dose for 50% of a population | b) The effective dose for 50% of a population |
| c) The dose that causes no effect in 50% of the population | d) The dose required for 50% absorption |
- (xiii) Select the mechanism of action of carbon monoxide toxicity
- | | |
|---|---|
| a) Inhibition of acetylcholinesterase | b) Binding to hemoglobin, reducing oxygen transport |
| c) Disruption of neurotransmitter release | d) Alteration of DNA structure |
- (xiv) Identify the primary target of lead toxicity in the body
- | | |
|-------------------|------------|
| a) Lungs | b) Liver |
| c) Nervous system | d) Kidneys |

(xv) What is the primary concern regarding bisphenol A (BPA)?

- a) It is a common food additive
- b) It may disrupt endocrine function
- c) It is safe for all consumers
- d) It has no known effects on health

Group-B

(Short Answer Type Questions)

3 x 5=15

- 2. Describe the function of CDSCO. (3)
- 3. Discuss preclinical studies with mentioning importance. (3)
- 4. Differentiate Type A ADR and Type B with the possible explanation. (3)
- 5. Discuss the criteria to conduct a cohort study. (3)
- 6. Hypoglycemia due to insulin is Type A ADR but drug allergy is Type B ADR. Analyze the statement to explain the concept of ADR. (3)

OR

RR for a population cohort study is 15 but AR is 93%. Analyze the statement. (3)

Group-C

(Long Answer Type Questions)

5 x 6=30

- 7. Discuss 5 points of schedule Y. (5)
- 8. Discuss five types of Adverse Drug Reactions with suitable examples. (5)
- 9. (5)

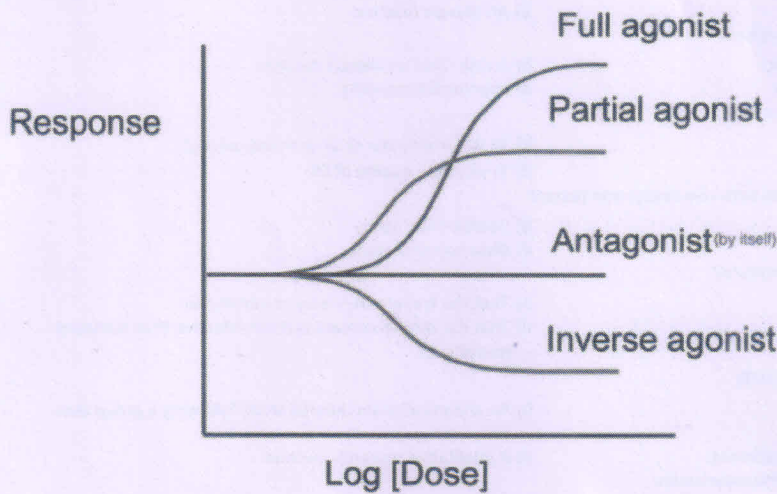
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	Cohort	Cross-sectional
Study group	Population-at-risk	Entire population (or a sample)
Common Measures	Risks and Rates	Prevalence

c

Compare and contrast the cohort and cross sectional study.

10.



Illustrate the graph and explain all the terms used in the graph.

- 11. Analyze each problem (disease) to explain the type of ADR: Analgesic nephropathy, drug allergy, teratogenesis, adrenocortical insufficiency, Hypoglycemia due to insulin. (5)
- 12. Teratogenesis is type D ADR but Hypoglycemia due to insulin is type A ADR- analyze and compare the ADR with possible justification. (5)

OR

	Varicella	Non-case	Total
Vaccinated	a = 18	b = 134	152
Unvaccinated	c = 3	d = 4	7
Total	21	138	159

Estimate incidence rate and RR with proper explanation.

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