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# BRAINWARE UNIVERSITY

## Term End Examination 2025-2026
## Programme – M.Sc.(BI)-2025
## Course Name – Clinical Trials and Pharmacovigilance
## Course Code - MBI20406A
## ( Semester II )

**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) List the core responsibility of the FDA in clinical trials.
a) Conducting trials b) Monitoring hospital ethics
c) Ensuring drug safety and efficacy d) Publishing research articles

(ii) Classify a study in which the investigator determines the treatment or exposure received by participants.
a) Observational study b) Case-control study
c) Cohort study d) Interventional study

(iii) Recognize the primary objective of Phase I clinical trials.
a) Safety and dosage assessment b) Efficacy testing
c) Post-marketing surveillance d) Comparative effectiveness

(iv) Report the primary purpose of inclusion and exclusion criteria in clinical trials.
a) To define an appropriate and safe study population b) To ensure ethical approval
c) To maximize sample size d) To simplify statistical analysis

(v) Recognize the body responsible for ethical approval of trials.
a) Sponsor b) Regulatory authority
c) Investigator d) Institutional Ethics Committee

(vi) Evaluate the suitability of large sample sizes for detecting small effects.
a) Highly suitable b) Moderately suitable
c) Not suitable d) Irrelevant

(vii) Recognize which protocol component defines outcome measures.
a) Timelines b) Study population
c) Assessments and endpoints d) Administrative details

(viii) Differentiate CRFs from source documents.
a) CRFs are original records b) Source documents summarize CRFs
c) CRFs capture data from source documents d) Both are identical

(ix) Critique the function of essential trial documents during regulatory inspections.

a) Recruitment facilitation
b) Budget validation
c) Statistical review
d) Evidence of proper trial conduct

(x) Recognize the key feature of an audit trail.

a) Tracking data creation and modification
b) Data visualization
c) Query generation
d) Data mining

(xi) Select the main function of clinical data backup.

a) Data analysis
b) Protection against data loss
c) Query resolution
d) SAE reporting

(xii) Determine the most appropriate tool for real-time remote data entry.

a) Paper CRF
b) Spreadsheet
c) EDC system
d) Statistical software

(xiii) Examine why audit trails are critical during regulatory inspections.

a) Ease of recruitment
b) Faster analysis
c) Verification of data integrity
d) Sample size increase

(xiv) Choose the primary role of WHO-ART in pharmacovigilance.

a) Standardized ADR terminology
b) Signal detection
c) Risk assessment
d) Data mining

(xv) Infer the regulatory risk of poor post-marketing surveillance.

a) Faster approvals
b) Reduced cost
c) Improved compliance
d) Market withdrawal of the drug

## Group-B

(Short Answer Type Questions) 3 x 5=15

2. State the defining feature of a crossover clinical trial design. (3)
3. Explain the importance of randomization and blinding in clinical trials. (3)
4. Evaluate the effectiveness of auditing in ensuring clinical trial compliance. (3)
5. Determine the appropriate pharmacovigilance method for actively monitoring adverse events in a defined patient group. (3)
6. Analyze the integration of pharmacovigilance with clinical trial data. (3)

**OR**

Differentiate between MedDRA and WHO-ART with respect to their impact on pharmacovigilance data analysis. (3)

## Group-C

(Long Answer Type Questions) 5 x 6=30

7. Summarize the key principles and objectives of ICH-GCP guidelines. (5)
8. Define bioavailability and bioequivalence, and discuss their significance in generic drug development. (5)
9. Differentiate between paper-based and electronic CRFs (eCRFs) in terms of data quality and regulatory compliance. (5)
10. Develop and justify site selection and investigator qualification criteria for a multicenter clinical trial. (5)
11. Evaluate the role of data management systems in ensuring confidentiality and data security in clinical trials. (5)
12. Define IND application and analyze the role of preclinical studies in supporting IND submission. (5)

**OR**

Describe the design of a cross-sectional study and evaluate its advantages and disadvantages in population-based research. (5)