



BRAINWARE UNIVERSITY

Term End Examination 2023-2024

Programme – B.Sc.(PA)-2021

Course Name – Basic of Clinical Research

Course Code - BPAC602

(Semester VI)

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) Pharmacodynamics involves the study of following EXCEPT _____ Select the correct option
 - a) Biological and therapeutic effects of drugs
 - b) Absorption and distribution of drugs
 - c) Mechanism of drug action
 - d) Drug interactions
 - (ii) What does "affinity" mean?
 - a) A measure of how tightly a drug binds to plasma proteins
 - b) A measure of how tightly a drug binds to a receptor
 - c) A measure of inhibiting potency of a drug
 - d) A measure of bioavailability of a drug
 - (iii) What type of monitoring can a study team perform to identify possible issues with data quality or integrity?
 - a) For-cause auditing
 - b) Internal monitoring System
 - c) Random monitoring System
 - d) None of these
 - (iv) Quality Control (QC) of study data should occur; Select the correct option.
 - a) on a random basis by an auditor
 - b) on a regular basis by the study team
 - c) on a pre-determined basis by the IC QA monitor
 - d) None of these
 - (v) Which of the following is the main point of difference between primary data and secondary data?
 - a) The collection of secondary data is costlier and more time consuming when compared to primary data
 - b) The secondary data is always original whereas the primary data is not
 - c) The primary data is much more reliable than secondary data because it is collected directly from respondents
 - d) None of these
 - (vi) Which of the following is a branch of CDL; Select the correct option.
 - a) New Delhi
 - b) Kolkata

- c) Faridabad
d) Bangalore
- (vii) Which of the following is a part of 4 M's of quality manufacturing
a) Machine
b) Mechanism
c) Manufacturing
d) Modeling
- (viii) Recognize the era in which randomized controlled trials became widely accepted as the gold standard for clinical research.
a) 19th century
b) 20th century
c) 18th century
d) 21st century
- (ix) Identify the primary purpose of blinding in a clinical trial.
a) To deceive participants
b) To reduce bias
c) To increase costs
d) To ensure protocol compliance
- (x) Choose the correct hypothesis testing method used in clinical research.
a) Chi-square test
b) T-test
c) ANOVA
d) All of the above
- (xi) Recognize the primary goal of phase III clinical trials.
a) To establish safety profile
b) To test drug efficacy
c) To monitor long-term effects
d) To evaluate bioavailability
- (xii) Recognize the term for the study design where participants are followed over a period of time to observe outcomes.
a) Cross-sectional study
b) Case-control study
c) Cohort study
d) Experimental study
- (xiii) Recognize the role of statistical analysis in clinical research.
a) Determining the efficacy of a new drug
b) Ensuring participant safety
c) Writing informed consent forms
d) Recruiting study participants
- (xiv) Choose the term that refers to "a substance or procedure with no therapeutic effect, used as a control in research."
a) Informed consent
b) Placebo effect
c) Blinding
d) Randomization
- (xv) Choose a study design suitable for investigating prevalence and associations.
a) Descriptive
b) Longitudinal
c) Experimental
d) Case report

Group-B

(Short Answer Type Questions)

3 x 5=15

2. Write a short note on Drug-Drug interaction? (3)
3. Explain the definition and scope of clinical research, highlighting its importance in advancing medical knowledge and improving patient care outcomes? (3)
4. Write about randomization and blinding in clinical research, explaining their roles in minimizing bias and ensuring the validity of study results? (3)
5. Classify the antihypertensive drugs acting on RAAS pathway (3)
6. Write a short note on antimicrobial drug? (3)

OR

Write in brief about combination therapy to treat hypertension? (3)

Group-C

(Long Answer Type Questions)

5 x 6=30

7. Explain what characterizes bioavailability? Give examples of drugs with different bioavailability. What is the bioavailability when it is given intravenously? (5)
8. Develop a comprehensive definition of clinical research and justify its importance in advancing medical knowledge and improving patient care. (5)

9. Solve hypothetical scenarios involving hypothesis testing in clinical research and explain how statistical methods are used to analyze data and draw conclusions. (5)
10. Debate the merits of different methods for representing clinical research data, such as tables, graphs, and charts, and justify your preferred approach. (5)
11. Describe the fundamental components integral to conducting clinical research and explain their roles in ensuring validity and reliability. (5)
12. Report on various clinical research study designs, including observational studies, randomized controlled trials, and cohort studies, and explain when each is most appropriate. (5)

OR

Rewrite the concept of randomization and blinding in clinical trials to highlight their importance in minimizing bias and ensuring reliable results. (5)
