(*University of Choice*)

MASINDE MULIRO UNIVERSITY OF SCIENCE AND TECHNOLOGY (MMUST)

MAIN CAMPUS

UNIVERSITY EXAMINATIONS

2022/2023 ACADEMIC YEAR

THIRD YEAR SECOND SEMESTER MAIN EXAMINATIONS

FOR THE DEGREE OF BACHELOR OF SCIENCE MEDICAL BIOTECHNOLOGY

COURSE CODE: BMB 422

COURSE TITLE: MODERN DRUG DEVELOPMENT

DATE: 18TH APRIL 2023 **TIME: 8.00 – 10.00PM**

INSTRUCTIONS TO CANDIDATES

This paper is divided into three sections, **A B** and **C,** carrying respectively: Multiple Choice Questions (**MCQs**), Short Answer Questions (**SAQs**) and Long Answer Questions (**LAQs**). **Answer all questions. DO NOT WRITE ON THE QUESTION PAPER.**

TIME: 2 Hours

MMUST observes ZERO tolerance to examination cheating

This Paper Consists of 4 Printed Pages. Please Turn Over

SECTION A: Multiple Choice Questions (20 Marks)

1. Which of the following represents the correct order of the four main phases in modern drug discovery?
    a. Pre-clinical research, clinical development, molecule discovery post marketing surveillance
    b. Pre-clinical research, Molecule discovery, clinical development, post marketing surveillance
    c. Molecule discovery, pre-clinical research, clinical development, post marketing surveillance
    d. Molecule discovery, pre-clinical research, post marketing surveillance, clinical development
2. Target identification finds a:
    a. Gene or protein that plays a significant role in disease
    b. Novel drug molecule
    c. Novel method of treatment
    d. New emerging disease
3. Ideal drug targets should have all of the following characteristics EXCEPT:
    a. Specific
    b. Capable of meeting clinical and commercial requirements
    c. Drugable
    d. Have many of target effects
4. All of the following can be used to validate drug targets EXCEPT:
    a. disease association
    b. FDA approval
    c. cell-based models
    d. signalling pathways analysis
5. Which one of the following is an important modern source of drug discovery targets?
    a. Traditional medicine men
    b. Sanger Whole Genome CRISPER library
    c. Pharmacology literature books
    d. Physiology journals
6. Which one of the following is NOTdone in the preclinical stage of drug development?
    a. Hit discovery
    b. Dose range finding
    c. Determination of ADME parameters
    d. Formulation optimization
7. Which of the following tools is used for post marketing monitoring?
    a. FDA Adverse Event Reporting System (FAERS) database
    b. FDA clinical trials data base
    c. National drug guidelines
    d. Ensemble data base
8. New drug applications may fail because of the following reasons EXEPT
    a. toxicity
    b. low efficacy
    c. inadequate drug performance
    d. cost of the new drug

9. New drug application (NDA) is submitted to the FDA after
    a. clinical trials demonstrate drug safety and efficacy
    b. clinical trials demonstrate drug safety and inefficacy
    c. preclinical data demonstrate efficacy
    d. after obtaining pharmacokinetic data

10. In the USA, Biologics License Application (BLA) is reviewed and approved by?
    a. FDA's Center for Biologics Evaluation and Research (CBER)
    b. FDA's Center for Drug Evaluation and Research (CDER)
    c. National drug authority
    d. National institutes of health
11. Which of the following is NOT a purpose of reproductive toxicity studies during drug development?
    a. to test the acute toxicity of the drug compound
    b. detect negative effects on embryonic developement
    c. to determine the negative effects of the compound on post-natal development
    d. the effects of the drug on fertility
12. All of the following are test that can be used to determine mutagenic effects of candidate drug compounds EXCEPT:
    a. Ames test
    b. Mouse Micronucleus Test
    c. Chromosomal Aberration Test
    d. Trinder's test
13. An Investigative New Drug (IND) application is prepared during which stage of drug development?
    a. Pre-clinal stage
    b. Drug discovery stage
    c. Post marketing stage
    d. Phase 1 clinical trial stage
14. Which one of the following is NOT true about phase I clinical studies?
    a. The drug candidate is tested for the first on humans
    b. involves less than 100 volunteers
    c. research participant are lean healthy male are recruited
    d. Involves testing of the drug candidate in non-human primates

15. In a single blind random clinical trial:
    a. the investigator but not the study participants know which treatment has been allocated
    b. the participants know which treatment has been allocated
    c. neither the investigator nor the study participant is aware of treatment assignments
    d. the participants are blind
16. Which of the following is strength of a randomized controlled clinical trial?
    a. Ethical constraints
    b. Expensive and time consuming
    c. Inefficient for rare diseases

d. Enables blinding and therefore minimizes bias

17. All of the following are advantages of randomization in clinical trials EXCEPT:
    a. Eliminates confounding
    b. Eliminates selection bias
    c. Gives validity in statistical tests based on probability theory
    d. Does not guarantee comparable groups

18. Which of the following is not a randomization methods in clinical trials?
    a. Simple randomisation
    b. Block randomisation
    c. Stratified randomisation
    d. Double blinding
19. Which of the following is a common tumor cell line used in testing novel compounds for colon cancer
    a. NCI-N87 cell line
    b. Jurkat cell line
    c. Saos-2
    d. Dukes type B cell line
20. Which of the following is a common tumor cell line used in testing novel compounds for lung cancer
    a. NCI-N87 cell line
    b. Jurkat cell line
    c. SPC A-1
    d. MCF-7

SECTION B: Sort Answer Questions (40 Marks)

1. Define the following terms in relation to drug development
    a. Drug discovery **(1 mark)**
    b. Randomised control trial (RCT) **(1mark)**
    c. Double blinding **(1mark)**
    d. Lead compound **(1 mark)**
2. With an aid of a diagram illustrate the steps/stages of modern drug development **(5 marks)**
3. Describe four reasons that may lead FDA not to approve new drug applications **(8 marks)**
4. Differentiate between activity- and in silico- based approaches of drug repurposing **(10 marks)**
5. Describe four methods for randomizing the allocation of subjects to intervention and control groups in a clinical trial **(8marks)**
6. Outline five quality control measures in randomized clinical trials **(5 marks)**

SECTION C: Long Answer Questions (60 marks)

1. Discuss in detail how you would develop a new antimalarial drug from medicinal plants that are used local for traditional medicine **(20 Marks)**
2. Describe four animal models used in anti-cancer drug discovery and development **(20 Marks)**
3. Discuss in details the preclinical toxicity studies that must be conducted during new drug development **(20 marks)**