Question Paper

Exam Date & Time: 19-May-2023 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Pharmacovigilance [PPR-BP805ET -S3]

Marks: 75 **Duration: 180 mins.**

I Multiple Choice Questions (MCQs)

Answer all the questions. Section Duration: 30 mins

1) Adverse Drug Reactions, that are pharmacologically related and dose-dependent are categorized as ---------- (1)

- Type A
- Type B
- Type C
- Type D

2) Pharmacovigilance is a branch of science including activities related to, (1)

- Detection, control, and prevention of adverse drug reactions
- Detection, control, and prevention of adverse drug reactions
- Detection, evaluation, control, and prevention of adverse drug reactions
- Evaluation, Control, and Reporting of adverse drug reactions

3) The incidence adverse drug reaction (ADR) of more than 10 percent is called ..... (1)

- Common ADR
- Rare ADR
- Very common ADR
- Very rare ADR

4) The followings are specific aims of pharmacovigilance, EXCEPT, (1)

- Contribute to the assessment of benefits & harm
- Improve patient care and safety
- Improve public health and safety
- Promote sales and marketing of the drug

5) Based on the severity of the adverse drug reaction (ADR), the ADR either directly or indirectly leads to the death of the patient, (1)

- Level 1
- Level 3
- Level

5
Level 7

6) According to causality assessment based on modified Naranjo's scale, how many categories of ADRs? (1)

2
4
6
8

7) A rich and highly specific standardized medical terminology to facilitate sharing of regulatory information internationally for medical products used by humans, (1)

MedDRA
MedWatch
VigiFlow
VigiLyze

8) Which of the following is not included in the WHO Drug Dictionary ..... (1)

Herbal remedies
Vaccine
Blood products
Food Products

9) The third level of ATC classification refers to ..... (1)

Anatomical
Chemical subgroup
Chemical substance
Pharmacological

10) The following causes are vaccine-related vaccine failure, EXCEPT, (1)

Incomplete coverage of strains
Vaccine is not 100% efficacious
Vaccine-vaccine interactions
Waning immunity

11) "The occurrence of the specific vaccine-preventable disease in a person who is appropriately and fully vaccinated taking into account the incubation period and the normal delay for the protection to be acquired as a result of immunization" is called, (1)

Confirmed clinical vaccine failure
Confirmed immunological vaccine failure
Suspected clinical vaccine failure
Suspected immunological vaccine failure

12) The national regulatory authority is the agency ensures the following aspects of vaccines, EXCEPT, (1)

Efficacy
Promotion
Quality
Safety

13) The Cohort studies are generally, (1)

Prospective

Retrospective
Can be both
Monitor one time

14) Cross-sectional studies, (1)

Are not useful for ecological analysis
Have historic controls
Outcomes and exposure at the same time
Select participants without exposure

15) The communication between public, and healthcare professionals are different, (1)

Public demand both information and transparency, prioritize the benefit-risk balance
Public demand information and transparency
Public prioritize the balance between benefit-risk
None of the above

16) Most crises result from, (1)

Severe non-compliance to regulations
Severe non-compliance to established standards
Severe compliance to fundamental ethical principles
Both A & B

17) Most of the medicines are metabolized by the enzyme, (1)

CYP1A2
CYP2C19
CYP2C9
CYP2D6

18) Genotoxicity studies should be completed before which of the following Phase of clinical trial ---------- (1)

Phase 1
Phase 2
Phase 3
Phase 4

19) In Drug and Cosmetic Act, schedule X refers ---------- (1)

Biologicals
GMP
Narcotics
Prescription Drugs

20) Approval of a trial protocol and safeguard of rights, safety and well-being of all trial subjects in the clinical trial monitored by ---------- (1)

CDSCO
DCGI
Ethics committee
Investigator

II Long Answers

Answer all the questions.

1)	Define adverse drug reactions (ADRs). Discuss the role of pharmacists in monitoring ADRs.	(10)
2)	Explain in detail ICH standards for Post-approval expedited reporting.	(10)

III Short Answers

Answer all the questions.

1)	Describe the structure of ATC system and explain the purpose of ATC/DDD system.	(5)
2)	Write a note on MedRA coding.	(5)
3)	Write a note on Pharmacovigilance in CRO.	(5)
4)	Discuss vaccine life cycle.	(5)
5)	Describe method of cross sectional studies used in ADR monitoring.	(5)
6)	Explain about an ideal communication process.	(5)
7)	Write a note on Drug safety evaluation in pregnancy.	(5)

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