Question Paper

Exam Date & Time: 20-May-2024 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Pharmacovigilance [PPR-BP805ET -S1]

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

I Multiple Choice Questions (MCQs)

Answer all the questions. Section Duration: 30 mins

1) Insulin-induced hypoglycemia is an example for ..... type of ADR. (1)

- Type A
- Type B
- Type D
- Type X

2) Reactions Weekly is an example for ..... drug information resources. (1)

- Primary
- Secondary
- Tertiary
- Others

3) Clinically validated international medical terminology used by regulatory authorities and the regulated biopharmaceutical industry called as ..... (1)

- Eudravigilance
- MedDRA
- Vigiflow
- WHO Dictionary

4) Which of the following is NOT included in the WHO Drug Dictionary ..... (1)

- Blood products
- Food Products
- Herbal remedies
- Vaccine

5) Largest database of pharmacovigilance for individual case safety reports in the world is, (1)

- VigiBase
- VigiFlow
- VigiLyze
- WHO Drug Global

6) Which of the following falls under the highest level of MedDRA hierarchy? (1)

- High-Level Term
- Lowest Level Term

Low-level Term
System Organ Class

7) ATC system is NOT suitable for, (1)

Decision about reimbursement
Drug consumption statistics globally
Drug utilization studies
Tool for drug quality use

8) Transmission of infection by contaminated multidose vial of vaccine is an example for, (1)

Coincidental event
Immunization error-related reaction
Vaccine product-related reaction
Vaccine quality defect-related reaction

9) The basic crisis management process include all, EXCEPT, (1)

Assess the risk
Identify the risk
Initiate preventive measures
Loss of resources

10) Sentinel sites are, (1)

Cost effective
For Passive reporting
Part of spontaneous reporting system
Supported by electronic methods

11) The following is an active surveillance method for adverse drug reaction monitoring. (1)

Case series
Drug event monitoring
Spontaneous reports
Stimulated reporting

12) Cross-sectional studies, (1)

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

13) Who develop vaccine information statement (VIS) and distributes them to state and local health departments as well as individual providers in US? (1)

CDC
NIH
US-FDA
WHO

14) Case series, (1)

Are small publishable unit

Is helpful to understand drug effect
Part of active surveillance
Will generate hypothesis

15) As per Schedule Y, the timeline for reporting serious adverse events by the investigator to the ethics committee will be ..... (1)

24 Hours
7 Days
12 Days
14 Days

16) The enzyme that metabolizes most of the medicines is ..... (1)

CYP1A2
CYP2C19
CYP2C9
CYP2D6

17) The pharmacogenetic test will identify those who are vulnerable to hemolysis with certain drugs is, (1)

DPD deficiency
G6PD deficiency
HLA-B variants
UGT1A1 variants

18) As per schedule Y, application for permission of import of new drug explained in ..... (1)

122-A
122-B
122-DA
122-E

19) 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

20) Which one of the drugs is an example for pregnancy category X? (1)

Methyldopa
Misoprostol
Pantoprazole
Ranitidine

II Long Answers

Answer all the questions.

1) Discuss any two methods for causality assessment of adverse drug reactions (ADRs). (10)

2) Explain various phases of clinical trials with its sample size and objectives. (10)

III Short Answers

Answer all the questions.

1) Define Pharmacovigilance. How to recognize an Adverse drug reaction? (5)

2)	Discuss the establishment of pharmacovigilance program in a hospital.	(5)
3)	Discuss briefly on International Classification of Diseases (ICD).	(5)
4)	Explain the importance of communication in drug safety crisis management.	(5)
5)	Describe the methods of passive surveillance with their merits and demerits.	(5)
6)	Explain the genetic polymorphism causing drug safety issues.	(5)
7)	Write a note on CIOMS working group.	(5)

-----End-----