Time: 3 Hrs **Marks: 80**

Q. 1 Attempt all Multiple-Choice Questions (MCQ) **20M**

Sr No	Questions		Options
1	The IRB should consist at least ---- members	a	Seven
		b	Five
		c	Six
		d	Four
2	Which person is responsible for the conduct of the clinical trial at a trial site?	a	Investigator
		b	Clinical Research Associate
		c	Clinical Research coordinator
		d	Sponsor
3	An individual, authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial is called as:	a	Clinical Research Associate
		b	Trial Monitor
		c	Impartial Witness
		d	Legally Acceptable Representative
4	Which of the following is a type of comparative studies	a	Cohort studies
		b	Randomized trials
		c	Qualitative studies
		d	Test controlled studies

5	The Science of Detection, Assessment, Understanding & Prevention of the adverse effects of Medications is known as:	a	Pharmacovigilance.
		b	Clinical Trails.
		c	Observational study.
		d	Qualitative study
6	Thalidomide tragedy occurred in the Year	a	1960
		b	1940
		c	1935
		d	1970
7	Center for Pharmacovigilance Program of India is located at:	a	IPC, Ghaziabad
		b	CDSCO, New Delhi
		c	AIIMS, New Delhi
		d	CDL, Kolkata
8	Anticoagulants will show which type of Adverse Drug Reaction?	a	Augmented
		b	Bizarre
		c	Chemical
		d	Delayed
9	Cross sectional study is carried out	a	At the same time point
		b	In same disease group
		c	In same gender
		d	In different disease group
10	Which one of the following is an Activity associated with Pharmacovigilance?	a	Vaccine Safety Surveillance
		b	Pre-clinical Drug Development
		c	Translational Research
		d	Phase I Clinical Study
11	Naranjo scale method of causality assessment is	a	Algorithmic method
		b	Probabilistic method
		c	Global Introspection.
		d	Algebraic Method

12	Schedule Y is related to:	a	Clinical trials
		b	Pricing Policy of Drugs
		c	Pre-clinical Drug Development
		d	Drug Utilization Regulations
13	ICSR stands for:	a	Individual Case Safety Report
		b	Internal Case Study Repository form
		c	International Clinical Study Report
		d	Internal Case Safety Report
14	CDSCO is located at:	a	New Delhi
		b	Kolkata
		c	Chennai
		d	Mumbai
15	WHO-ART has	a	4 levels hierarchical structure
		b	10 levels hierarchical structure
		c	5 levels hierarchical structure
		d	6 levels hierarchical structure
16	What is the meaning of Causality?	a	Relationship between suspect product and adverse drug event
		b	Relationship between suspect product and outcome of adverse event
		c	Relationship between dose of suspect product and adverse drug event
		d	Relationship between dose of suspect product and outcome of adverse reaction

17	What is meant by a blind subject?	a	The subjects do not know which study treatment they receive
		b	Patients injected with placebo and active doses
		c	Fake treatment
		d	Signed document of the recruited patient for the clinical trial procedures
18	Pharmacovigilance Programme of India started in the year:	a	2010
		b	2009
		c	2005
		d	2012
19	An Individual or Organization responsible for the Initiation, Management and Finance of a Clinical Trial is called as:	a	Investigator
		b	Sponsor
		c	Auditor
		d	Monitor
20	Type I Hypersensitivity Reactions are _____	a	IgE mediated
		b	Caused by tissue injury
		c	Caused when T-cells bind to a specific antigen
		d	Caused by cytotoxic antibodies

Q 2. Attempt any one question **12 M**

1. a. Enlist different types of Adverse Drug Reactions. Differentiate between Type A and Type B ADR. **6 M**

   b. Write a note on Management of Adverse Drug Reactions. **6 M**

2. a. Differentiate between Active and Passive Surveillance. Add a note on Spontaneous Reporting of ADR. **6 M**

   b. Discuss the Observational studies in detail. **6 M**

Q 3. Attempt any four questions. **48 M**

1. Discuss the structure and content of Clinical Trial Protocol in detail.
2. Elaborate on National Pharmacovigilance Programme in India.
3. Elaborate on various designs of clinical trials in detail.
4. Explain the Roles and Responsibilities of Principal Investigator in Clinical Trials.
5. Explain the Concepts and Applications of Pharmaco-economics in detail.
