MPL

F.Y. M.Pharma

13/8/2025

Duration: 3 Hrs **Total marks: 75**

N.B.: 1. All questions are compulsory
2. Figures to the right indicate full marks

Q. 1 Attempt all multiple-choice questions (MCQ) **20M**

No	Questions		Options
	As per Schedule Y and ICMR guidelines, which of the following statements is true regarding the responsibilities of an Ethics Committee?	a	The EC must report only SAE-related decisions to the sponsor
		b	The EC is not involved in ongoing review after approval
		c	The EC must maintain records of meetings and decisions for at least 3 years
		d	The EC decisions do not need to be documented in writing
	The following is a core principle of ICH-GCP guidelines	a	Maximising data manipulation
		b	Subject confidentiality must be protected
		c	Compensation must not be provided
		d	Trials can skip ethical approvals
	The Indian guideline governing the ethical conduct of biomedical research involving human participants	a	Schedule M
		b	ICH E2E
		c	ICMR Guidelines
		d	CDSCO-GCP
4	As per Schedule Y, which of the following is required before initiating a clinical trial in India?	a	US FDA approval only
		b	Ethics Committee approval and DCGI permission
		c	CDSCO manufacturing license only
		d	Investigator qualification only
5	Among the following, who is mainly responsible for the coordination of day-to-day clinical trial activities	a	Investigator
		b	Study Coordinator
		c	Sponsor
		d	Ethics Committee

6	The document which provides a comprehensive summary of the clinical and non-clinical data on an investigational product is known as	a	Case Report Form
		b	Protocol
		c	Clinical Study Report
		d	Investigator Brochure
7	Which of the following is TRUE about Adverse Drug Reactions (ADRs)?	a	They always occur at recommended doses
		b	They are always predictable
		c	They are always preventable
		d	They can be predictable or unpredictable
8	The guidelines which provide structure for writing Clinical Study Reports is	a	ICH E3
		b	ICH M4
		c	ICH E2A
		d	WHO TRS 498
9	Type B ADR refers to	a	Dose-dependent and predictable reaction
		b	Unexpected and not dose-related
		c	Beneficial effect of a drug
		d	Withdrawal symptoms
10	A Phase III clinical trial is primarily designed to:	a	Test drug metabolism in animals
		b	Assess long-term safety after approval
		c	Confirm efficacy in large populations and adverse effects
		d	Test on healthy volunteers only
11	An organisation hired by sponsor to manage clinical trial operations is	a	CRO (Contract Research Organisation)
		b	WHO
		c	IRB
		d	FDA

12	A person primarily responsible for the conduct of a clinical trial at the site	a	Sponsor
		b	Ethics Committee
		c	Principal Investigator
		d	Research Coordinator
13	Pharmacovigilance focuses on	a	Drug discovery
		b	Drug manufacturing
		c	Drug safety monitoring
		d	Drug pricing
14	The WHO Programme for International Drug Monitoring is coordinated by	a	CDSCO,India
		b	FDA, USA
		c	EMA, Europe
		d	Uppsala Monitoring Centre, Sweden
15	The global database maintained by the WHO for ADR reports is	a	PubMed
		b	ToxNet
		c	VigiBase
		d	DrugBank
16	The Pharmacovigilance Programme of India (PvPI) is coordinated by	a	Indian Medical Association
		b	CDSCO
		c	Indian Council of Medical Research
		d	Indian Pharmacopoeia Commission (IPC)
17	Incidence and prevalence are key measures used in which branch of pharmacy?	a	Pharmacogenomics
		b	Pharmacoepidemiology
		c	Medicinal Chemistry
		d	Pharmacoeconomics
18	According to ICH E2E, major limitation of the spontaneous reporting system is	a	High cost of data collection
		b	Incomplete regulatory compliance
		c	Under-reporting and reporting bias
		d	Lack of qualified reporters

19	Bayesian methods in pharmacovigilance are used to	a	Manufacture vaccines
		b	Establish causality using probability
		c	Collect consent from patients
		d	Predict dosing in children
20	The event which led to the establishment of formal international pharmacovigilance systems is	a	The introduction of antibiotics
		b	The discovery of penicillin
		c	The thalidomide-induced birth defects in the
		d	The banning of DDT

Q 2. Attempt any two questions **10×2= 20M**

1. Discuss the structure and content of the Clinical Trial Protocol in detail.
2. Explain in detail the concepts of passive and active surveillance in pharmacovigilance. Compar their methodology, strengths, and limitations with suitable examples.
3. Explain the responsibilities of key players involved in clinical trials

Q 3. Attempt any seven questions **5×7= 35M**

1. Define Institutional Review Board. Discuss the Composition and Functions of the same.
2. Elaborate on the Structure and Content of the Informed Consent Form.
3. Write a note on – Contract Research Organisation and its Management.
4. Enlist different types of Adverse Drug Reactions. Differentiate between Type A and Type ADR
5. Define an Investigator's Brochure (IB). List any four key elements included in the IB and the relevance.
6. Elaborate on statistical methods to evaluate medication safety data.
7. Discuss difference softwares used in pharmacovigilance
8. Explain the Concepts and Applications of pharmacoeconomics in detail.
9. State the significance of Medication Safety Evaluation. Give a brief account of roles an responsibilities in Pharmacovigilance

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