# School of Basic and Applied Sciences

**BioScience**

**ETE - Jun 2023**

**Time : 3 Hours** **Marks : 50**

**Sem II - MBACNT2005 - Fundamental of Clinical Research**

*Your answer should be specific to the question asked*

*Draw neat labeled diagrams wherever necessary*

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|---|---|---|---|
| **1.** | Describe adverse drug reaction (ADR). | K1 CO1 | (2) |
| **2.** | Describe Inspection in clinical studies. | K2 CO4 | (2) |
| **3.** | Define monitoring in clinical research. | K1 CO3 | (2) |
| **4.** | Describe ICF. | K2 CO5 | (2) |
| **5.** | Describe serious adverse event. | K2 CO2 | (2) |
| **6.** | Express the 13 principles of ICH_GCP. | K3 CO2 | (5) |
| **7.** | Describe the Serious Adverse Event (SAE) and Adverse Drug Reaction. | K3 CO1 | (5) |
| **8.** | Evaluate the term trade mark and copy right in IPR. | K4 CO6 | (6) |
| **9.** | Express the Stakeholders in clinical trials. | K4 CO5 | (8) |
| **10.** | Demonstrate the Career Opportunities in Clinical trials. | K4 CO4 | (8) |
| **11.** | Describe the ICMR guideline and its importance. | K3 CO3 | (8) |