

**THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY**

**[M.PHARM 0922]**

**SEPTEMBER 2022  
(APRIL 2022 EXAM SESSION)**

**Sub. Code: 2988**

**M.PHARMACY DEGREE EXAMINATION  
SEMESTER - II (PCI New regulations 2016)  
PHARMACOLOGY - MPL  
PAPER IV – CLINICAL RESEARCH AND PHARMACOVIGILANCE**

*Q.P. Code : 262988*

**Time : Three hours**

**Answer ALL Questions**

**Maximum : 75 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. Define and discuss about different types of ADR. Write briefly about methods, assessment and management of ADR.
2. Discuss briefly about Clinical Trials, types, designs, RCT and Non RCT. Mention the role sponsor, coordinator, CRO and management.

**II. Write notes on:**

**(7 x 5 = 35)**

1. Define active and passive surveillance.
2. International classification of diseases.
3. Pharmacoepidemiology.
4. Cross Sectional studies.
5. Interpretation and Computation in clinical trials.
6. Role and responsibility of Pharmacovigilance.
7. Cost effective in Pharmacoeconomic studies.

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