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

[PHARMD 0424] **APRIL 2024** **Sub. Code: 3825**

PHARM 'D' AND PHARM. 'D' (POST BACCALAUREATE) DEGREE EXAMINATION
FIFTH YEAR (2009-2010 Regulation)
PAPER I – CLINICAL RESEARCH

Q.P. Code: 383825

Time: Three hours **Answer ALL Questions** **Maximum: 70 Marks**

I. Elaborate on: **(4 x 10 = 40)**

1. Explain briefly about drug development process.
2. Data management and its components.
3. Explain the various methods of post marketing surveillance.
4. Write in detail the central drug standard control organization guidelines.

II. Write notes on: **(6 x 5 = 30)**

1. Toxicological approaches to drug discovery process.
2. ICH-GCP guidelines.
3. What are the responsibilities of Clinical research associate?
4. Explain the process of Informed consent.
5. Different types of clinical trials.
6. Define the following:
   a) Case Report Form (CRF) b) Impartial witness c) Schedule-Y

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