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Drug Management System

Background:

Pharmaceutical companies face complex challenges in managing drug data, including monitoring drug safety, adverse event reporting, and regulatory compliance. Drug Management Systems (DMS) are designed to handle such tasks, particularly during premarket and post-market phases. The proposed Drug Management System will streamline case management related to adverse effects, drug interactions, patient history, and product-specific information. The Future Scope of this system can be expanded to report the cases to regulatory agencies to fulfil their regulatory obligations.

Purpose:

The main purpose of this Drug Management System is to provide a centralized platform for pharmaceutical companies to manage drug-related cases efficiently. This system will:

- 1. Ensure negative side effects are reported accurately across various drugs and devices.
- 2. Facilitate compliance with regulatory standards like FDA (Food and Drug Administration).
- 3. Enable efficient monitoring and data retrieval to enhance drug safety and decision-making processes.
- 4. Improve the speed and accuracy of data collection and analysis regarding patient outcomes.

Objectives:

- 1. Case Management: Manage adverse event cases efficiently across drugs, devices, and patients.
- 2. Regulatory Reporting: Facilitate standardized reporting of adverse event cases to regulatory bodies.
- 3. Decision Support: Provide data analytics and reporting features to assist pharmaceutical companies in making informed decisions regarding drug safety.
- 4. Communication: Enable better communication between manufacturers, healthcare providers, and regulatory bodies.

Scope:

This Drug Management System will be used exclusively for managing cases related to drug safety and adverse reactions. It will include:

- 1. Case Reporting: Recording and tracking adverse event cases related to various pharmaceutical products.
- 2. Product Information Management: Maintaining detailed information about the drugs, devices, or combination products.
- 3. Patient History: Capturing the medical history of patients related to specific drug reactions or treatments.