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 Scope of this system can be increased to report the cases to regulatory agencies to fulfill 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 accurate reporting of adverse drug reactions (ADR) across various drugs and devices.
2. Facilitate compliance with regulatory standards like FDA (Food and Drug Administration) and MHRA (Medicines and Healthcare products Regulatory Agency) requirements.
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. Data Integration: Integrate data from various sources such as clinical trials, patient history, and product development reports.
4. Decision Support: Provide data analytics and reporting features to assist pharmaceutical companies in making informed decisions regarding drug safety.
5. Streamlined 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.
4. Regulatory Compliance: Generation of reports as per regulatory guidelines (FDA, MHRA or any other).

Entities:

1. Case Master-Master record for case form.

2. Case Patient-Other relevant history for patient.

3. Case Product - Product information. Supertype to Drug and Device tables

4. Case Product Drug - Drug specific information for product.

5. Case Product Device - Device information.

6. Regulatory Agencies - reporting agencies

7. Case Report - Final report delivered to the responsible agency

8. Case Follow-up -follow-up information – Weak Entity

9. Case Dose Regimen - Individual dosage regimens for the case

10. Case Reporters - Reported information

11.User - Contains User information who works on the one more case and send reports to regulatory agencies.

ENTITIES DESCRIPTION:

1. Case Master

- **Attributes**:
  - case_id (Primary Key)
  - case_description (details of the adverse event)
  - case_date (date when the case was registered)
  - status (status of the case: open, closed, in progress)
  - severity (severity of the case: mild, moderate, severe)
- **Primary Key**: case_id
- **Relationships:** can generate case reports, contains case dose regimen information, cases assigned to user, is associated to case patient, may have case follow ups, is registered by reporter.

2. Case Patient

- **Attributes**:
  - patient_id (Primary Key)
  - patient_name
  - medical_history (medical background of the patient)
  - allergies (known allergies of the patient)
  - contact_info (contact details of the patient)
- **Primary Key**: patient_id
- **Relationships:** can have multiple cases (case master).

3. Case Product

- **Attributes**:
  - product_id (Primary Key)
  - product_name
  - product_type (drug or device)
  - manufacturer_name
  - expiry_date
- **Primary Key**: product_id
- **Relationships:** belongs to either case product drug or case product device, contains case dosage information.

4. Case Product Drug

- **Attributes**:
  - drug_id (Primary Key)
  - drug_name
  - dosage_form (form of the drug: tablet, injection)
  - strength (strength of the drug, e.g., 500mg)

    - route_of_administration (oral, intravenous, etc.)
- **Primary Key**: drug_id

5. Case Product Device

- **Attributes**:
    - device_id (Primary Key)
    - device_name
    - device_classification (class of the medical device)
    - device_model
    - manufacturer
- **Primary Key**: device_id

6. Regulatory Agencies

- **Attributes**:
    - agency_id (Primary Key)
    - agency_name
    - country (location of the agency)
    - contact_person
    - contact_info
    - regulation_code (specific code or guidelines followed by the agency)
- **Primary Key**: agency_id
- **Relationships:** can receive case reports.

7. Case Report

- **Attributes**:
    - report_id (Primary Key)
    - report_date (date when the report was generated)
    - report_status (pending, sent, acknowledged)
    - report_type (initial, follow-up, final)
- **Primary Key**: report_id
- **Relationships:** is submitted to regulatory agencies, contains information about cases (case master).

8. Case Follow-up (Weak Entity): A follow-up cannot exist without an associated case, making it a weak entity dependent on the Case Master.

- **Attributes**:
    - followup_id: Primary Key (unique identifier for each follow-up)
    - followup_date: Date when the follow-up occurred
    - followup_notes: Notes or information from the follow-up
    - status_update: Changes in the case status during follow-up
    - reported_by: Person who made the follow-up

- **Primary Key**: followup_id
- **Relationships:** is linked to case(case master), initiated by reporter.

9. Case Dose Regimen : The **Case Dose Regimen** serves as an **associative entity** between **Case Master** and **Case Product**, as a case can involve multiple products with different dosage regimens.

- **Attributes**:
  - regimen_id: Primary Key
  - dosage: Specific dosage information
  - frequency: How often the dosage is administered
- **Primary Key**: regimen_id
- **Relationships:** linked to case (case master), linked to specific product

10. Case Reporter

- **Attributes**:
  - reporter_id (Primary Key)
  - reporter_name
  - reporter_role (e.g., physician, pharmacist, etc.)
  - contact_info
  - reporter_notes (additional comments or observations from the reporter)
- **Primary Key**: reporter_id
- **Relationships:** can register/report cases, initiates follow-up.

11. Users (Strong Entity):

- **Attributes**:
  - user_id: Primary Key (unique identifier for each user)
  - user_name: Name of the user (e.g., an employee, doctor, or pharmacist)
  - role: The role of the user (e.g., admin, case manager, reporter)
  - contact_info: Contact details of the user
- **Primary Key**: user_id
- **Relationships:** works on cases (case master)

12. Assignment_Status:

- This will act as an relationship between **Users** and **Case Master** to log case assignment actions.
- It represents the status whether the user is assigned to the case or not .

ENTITY RELATIONSHIPS

1. Case Master

- **Case Patient**: Many-to-One (One/Many cases associated to one patient).
  Business Rule: Every case in the system is associated with exactly one patient data, capturing relevant medical details.
- **Case Report**: One-to-Many (A case can generate multiple reports).
  Business Rule: A case can generate multiple reports, each sent to a relevant regulatory agency.
- **Case Follow-up**: One-to-Many (A case can have multiple follow-ups).
  Business Rule: A case may require multiple follow-ups for additional information or status updates.
- **Case Dose Regimen**: One-to-Many (A case can have multiple dosage regimens).
  Business Rule: A case may include different dosage regimens for each product used by the patient.
- **Case Reporter**: Many-to-One (Many cases can be registered by one reporter).
  Business Rule: An individual (e.g., doctors, healthcare providers) may report information for multiple cases.
- **User**: Many-to-Many (Cases can be assigned to one/many users).

2. Case Patient

- **Case Master**: One-to-Many(One patient can have multiple cases).
  Business Rule: Every patient in the system can have one/more cases (case master)

3. Case Product

- **Case Dose Regimen**: One-to-Many(Product contains multiple dosage regimens based on the case).
- **Case Product Drug**: One-to-One (Each product can either be a drug or a device).
  Business Rule: If a product is classified as a drug, it will have a specific record in the **Case Product Drug** entity.
- **Case Product Device**: One-to-One (Each product can either be a device or a drug).
  Business Rule: If the product is a device, it must have a record in the **Case Product Device** entity.
  Case product is supertype to Drug and Device with total specialization

4. Case Product Drug

- **Case Product**: One-to-One (subtype to **Case Product)**

5. Case Product Device

- **Case Product**: One-to-One (subtype to **Case Product)**

6. Regulatory Agencies

- **Case Report**: Many-to-Many (Agency can receive one/many case reports).
  Business Rule: Each regulatory agency (e.g., FDA, MHRA) may receive multiple case reports from different cases.

7. Case Report

- **Case Master**: Many-to-One (Reports can contain information about one case).
- **Regulatory Agencies**: Many-to-Many(Reports can be send to one/many regulatory agencies).

8. Case Follow-up (Weak Entity)

- **Case Master**: Many-to-One (follow-ups can be linked to one case).
- **Case Reporter**: Many-to-One(Each follow-up case is initiated by a reporter).

9. Case Dose Regimen

- **Case Master**: Many-to-One (Dose regimens are linked to one case).
- **Case Product**: Many-to-One (Dose regimens are linked to one product).

10. Case Reporter

- **Case Master**: One-to-Many (Each reporter can register one or more cases).
- Case Follow-up: One to Many(Each reporter can initiate multiple follow-ups).

11. User (Strong Entity)

- **Case Master**: Many-to-Many (Users can work on multiple cases).

BASIC BUSINESS RULES:

1. **Case Reporting**: Every **Case** must be linked to at least one **Case Report**, which is then delivered to one or more **Regulatory Agencies**.
2. **Product Classification**: Each **Case Product** can either be a **Case Product Drug** or a **Case Product Device**, but not both. A product cannot exist without being classified under one of these two entities.

3. **Follow-up Management**: A **Case Follow-up** can only exist if it is related to an existing **Case Master**. Each follow-up record provides updates or additional information regarding the case.
4. **Dose Regimen Information**: Each **Case Dose Regimen** must be linked to a **Case Master**, indicating that at least one dosage regimen has been followed for the patient.
5. **Reporter Information**: Each case must have atmost one **Case Reporter** providing information, which could be from various sources such as physicians or healthcare providers.

ER (ENTITY RELATIONSHIP) DIAGRAM: