P3:Logical ERD Model

Description of Changes to the Initial ERD:

- **Normalization to Third Normal Form (3NF)**: The entire model is updated to eliminate any partial and transitive dependencies. Each entity now contains only attributes that are fully dependent on the primary key. Multivalued and composite attributes were also removed or transformed to meet the requirements of 3NF.

Criteria for 3NF:

1. No partial dependencies (every non-key attribute must depend on the whole primary key, not just part of it).

2. No transitive dependencies (no non-key attribute should depend on another non-key attribute).

Analysis of Key Entities:

1. Case:

i. Contains 'CaseID' (Primary Key) and attributes like 'PatientID', 'ReporterID', 'CaseDescription', 'CaseDate', 'Status', and 'Severity'.
ii. All attributes are fully dependent on the primary key 'CaseID'.
iii. PatientID', 'ReporterID' are foreign keys.

Conclusion: This entity is in 3NF.

2.User:

i. Contains 'UserID'(Primary Key),and attributes like 'UserName', 'Role', 'ContactNo'.

   Users can have roles: Case Manager, Associate, QualityAnalyst

ii. These attributes depend on the primary key 'UserID'.

Conclusion: This entity is in 3NF.

3. User Case Assignment:

i. This is an associative entity that breaks the many-to-many relationship between User and Case.
ii. It contains the primary key 'AssignmentId' and foreign keys 'UserId' and 'CaseId'.
iii. Attributes like 'Status', 'StartDate', and 'CompleteDate' are directly related to this assignment and depend on the primary key 'AssignmentId'.

Conclusion: This entity is in 3NF.

4.Case Report:

iii. Contains 'ReportID'(Primary Key),and attributes like 'Report Date', 'Report Status', 'Report Type'.
iv. These attributes depend on the primary key 'ReportID' and foreign key is CaseId.

Conclusion: This entity is in 3NF.

5.Regulatory Case Reports:

i. This associative entity resolves the many-to-many relationship between Regulatory Agency and Case Report.
ii. It contains the 'TrackingNum' (Primary key) and foreign keys as 'ReportID' and 'AgencyID'
iii. Attributes like 'SubmissionDate', 'ACKDate', 'Status', and are dependent on the 'TrackingNum' .

Conclusion: This entity is in 3NF.

6. Regulatory Agency:

i. Contains attributes like 'AgencyID' (Primary Key), 'AgencyName', 'Country', and 'RegulationCode'.
ii. These attributes are fully dependent on the primary key 'AgencyID', with no partial or transitive dependencies.

Conclusion: This entity is in 3NF.

7. Regulatory Agency Contact:

i. Contains 'PersonID' (Primary Key), 'FirstName', 'LastName', 'Email', 'Position', and 'AgencyID'.
ii. The attributes 'FirstName', 'LastName', 'Email', and 'Position' are fully dependent on the primary key 'PersonID'.
iii. 'AgencyID' is the foreign key referencing Regulatory Agency entity.

Conclusion: This entity is in 3NF.

8.Case Reporter:

i. Contains 'ReporterID' (Primary Key) and attributes like 'ReporterName', 'ReporterRole', 'ContactNo', and 'ReporterNotes'.
ii. These attributes are fully dependent on 'ReporterID'.

Conclusion: This entity is in 3NF.

9. Patient:

i. Contains 'PatientID' (Primary Key) and attributes like 'PatientName', 'MedicalHistory', 'Allergies', and 'ContactNo'.
ii. These attributes are dependent on the primary key 'PatientID'.

Conclusion: This entity is in 3NF.

10. Dose Regimen:

i. Contains 'RegimenID' (Primary Key) and foreign keys 'CaseID' and 'ProductID', along with attributes like 'Dosage' and 'Frequency'.
ii. Attributes are dependent on 'RegimenID'.

Conclusion: This entity is in 3NF.

11. Product:

i. Contains 'ProductID' (Primary Key) and attributes like 'ProductName', 'ProductType', 'ManufacturerName', and 'ExpiryDate'.
ii. All attributes depend on 'ProductID'.
iii. SuperType for Drug and Device.

Conclusion: This entity is in 3NF.

12.Drug and Device:

i. Both are subtypes of Product.
ii. The subtypes contain specialized attributes for drugs ('DosageForm', 'Strength', 'Route of Administration') and devices ('Classification', 'Model', 'Manufacturer'.).
iii. Each of these attributes are dependent on the corresponding primary key ('DrugProductID' and 'DeviceProductID'), which act as foreign keys from Case Product.

Conclusion: These entities are in 3NF.

13. Follow-up:

i. Contains 'FollowupID' (Primary Key), 'CaseID'(Foreign key), and attributes like 'FollowupDate', 'FollowupNote', 'StatusUpdate', and 'ReportedBy'.
ii. These attributes depend on the primary key 'FollowupID'.

Conclusion: This entity is in 3NF.

Description of 3NF Changes:

Regulatory Agency

- **Attributes**:
  - agency_id (Primary Key)
  - agency_name
  - country (location of the agency)
  - contactperson_id
  - first_name
  - last_name

- email
- position
- regulation_code (specific code or guidelines followed by the agency)

- **Primary Key**: agency_id

Step 1: Identify and remove any partial dependencies:In the current design, there are no partial dependencies, as the primary key (agency_id) uniquely identifies each attribute in the table.

Step 2: Identify and remove transitive dependencies: We look for attributes that depend on other non-key attributes rather than the primary key. In this case firstname,lastname,email,position are dependent on contactperson_id and could be considered a transitive dependency. These attributes describe information specific to the contact person.

Table 1: Regulatory_Agency

- **Attributes**:
  - AgencyId (Primary Key)
  - AgencyName
  - Country
  - RegulationCode

Table 2: Regulatory_Agency_Contact

- **Attributes**:
  - PersonId (Primary Key)
  - AgencyId (Foreign Key references Regulatory_Agency)
  - FirstName
  - LastName
  - Email
  - Position

Regulatory_Agency:

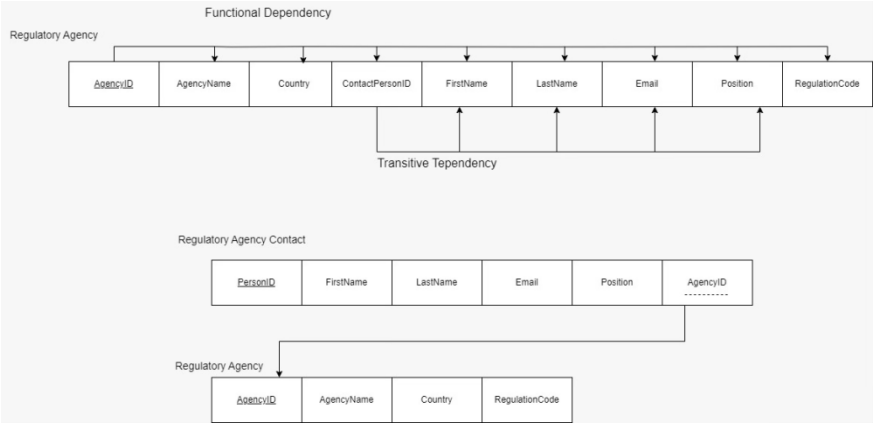
- This table now contains attributes that are specific to the agency itself, with the primary key being agency_id.
- Attributes like agency_name, country, and regulation_code are directly related to the agency and satisfy the requirement of 3NF, as they are all fully dependent on the primary key.

Regulatory_Agency_Contact:

This new table contains information about the contact person and their details, which are related to the agency but not directly part of its core attributes.

- By creating this table, we eliminate the transitive dependency of contact_person name,Email, position on agency_id. Now, these attributes

depend on PersonId, and the relationship between the agency and its contact details is managed through the agency_id foreign key.



Associative Entities :

In the original ERD design, there was a many-to-many relationship between **User** and **Case, Regulatory Agency** and **Case Report**. This occurs because multiple users (users are employees who work and evaluate the cases and generate necessary case reports) can be assigned to multiple cases, and each case can have multiple users working on it.

- **Associative Entity : User Case Assignment**

The **User Case Assignment** is introduced as an associative entity which resolves the many-to-many relationship. This allows us to break the relationship into two one-to-many relationships:

1. One user can have multiple case assignments.
2. One case can have multiple users assigned to it through the assignment entity.

- **Attributes**:
  - AssignmentId (Primary Key): This uniquely identifies each record in the **User Case Assignment** table.
  - Status: The current status of the assignment (New, in progress, complete).
  - StartDate: The date when the user was assigned to the case.
  - CompleteDate: The date when the user completed their assignment (if applicable).
  - UserId (Foreign Key): Links to the **User** entity, indicating which user is assigned to the case.
  - CaseId (Foreign Key): Links to the **Case** entity, indicating which case the user is working on.

By using this associative entity, we have successfully:

1. **Removed the many-to-many relationship** between **User** and **Case**.
2. Ensured that the model adheres to **Third Normal Form (3NF)** by eliminating redundancy and maintaining data integrity.
3. Allowed more detailed tracking of which users are assigned to which cases and their respective statuses and dates.

- **Associative Entity : Regulatory Case Reports** entity acts as an associative entity that resolves a many-to-many relationship between **Regulatory Agency** and **Case Report**.

A many-to-many relationship exists between the **Regulatory Agency** and **Case Report** entities:

1. **Multiple regulatory agencies** could receive reports about the same case.
2. A **single regulatory agency** could also receive multiple case reports over time.

To eliminate this many-to-many relationship, the **Regulatory Case Reports** entity is introduced as an associative entity, creating two one-to-many relationships:

1. One regulatory agency can be associated with multiple case reports.
2. One case report can be linked to multiple regulatory agencies through the **Regulatory Case Reports** entity.

Regulatory Case Reports Entity:

- **Attributes**:

  - TrackingID(Primary Key: A unique number used to track the progress of the case report.
  - ReportID (Foreign Key): Uniquely identifies each regulatory case report.
  - AgencyID (Foreign Key): Links to the **Regulatory Agency** entity, identifying which agency the case report is submitted to.
  - SubmissionDate: The date the case report was submitted to the regulatory agency.
  - ACKDate: The acknowledgment date ,Agency confirming that the report was received.
  - Status: The current status of the case report (e.g., 0-Pending, 1-Sent, 2-Success, 3-Error).

By using **Regulatory Case Reports** as an associative entity, we achieve the following:

1. **Remove the many-to-many relationship** between **Regulatory Agency** and **Case Report**.
2. Ensure that the database design adheres to **Third Normal Form (3NF)** by breaking down the relationships into two one-to-many relationships.

3. Provide a clear mechanism for tracking the status, submission, and acknowledgment of each case report submitted to different regulatory agencies.

Primary and Foreign Keys: All entities now have clearly defined primary keys, and foreign keys have been added to manage relationships between entities. This ensures referential integrity is maintained throughout the database. Below is the **Logical ERD Model** incorporating all the above mentioned points.

Logical ERD:

Relational Schema: