

DATA INTEGRITY IN THE PHARMACEUTICAL INDUSTRY

A Database Solution Approach

ABSTRACT

This paper presents a database solution aimed at improving data cleanliness and regulatory compliance in the pharmaceutical industry. The proposed tool leverages advanced database methodologies to ensure data integrity, enhance regulatory checks, and streamline compliance reporting. By implementing this solution, pharmaceutical companies can achieve higher levels of accuracy and operational efficiency in managing clinical trial data, ultimately leading to improved regulatory compliance and better patient outcomes.

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Project Deliverable 2

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Chosen Area: Pharmaceuticals

SECTION 1; AN INTRODUCTION

A. Chosen Area: Pharmaceuticals (Drug Administration and Market Analysis)

Pharmaceutical firms heavily depend on extensive data for various operations, ranging from interpreting clinical results to evaluating drug efficacy through real-world health metrics. Firms must ensure adherence to strict standards and changing legal requirements that will require continuous monitoring of data quality, as even minor errors could lead to legal repercussions, harm to reputation, and most importantly, endanger the well-being and lives of patients.

B. Data Management Problems: Data Integration and/or Standardization of Data; Data Quality Assurance and Accuracy/Completeness

The pharmaceutical and biotech industries grapple with the rigorous task of ensuring clinical trial records are accurate and aligned across various data sources which can be a real headache. Whether it is data from contract research organizations, central labs, or third-party sources, the need for clean, on-point and consistent data has become more complex and increasingly difficult to manage.

To keep data integrity in check, it's crucial for process owners to grasp how it affects products from both technical and regulatory standpoints. Sadly, many pharma firms miss the mark here. They overlook critical aspects like robust analytical procedures, controlling process parameters, data acquisition, interpretation methods, and oversight.

Regulatory changes add another layer of complexity. Leaders feel the weight of constantly shifting rules, making it trickier to stay on top. Adapting to these changes is a must, even though it's a headache. New data-related regulations can drive up costs, complicate things, and pose challenges in software development. Leaders also fret about cross-border data transfers and data localization issues, fearing they might stumble on the ever-changing regulatory terrain.

Note: The above data management issues encompass the scope of this paper, although there is a far more extensive list of issues plaguing pharmaceuticals and data management today which are not discussed in the following solutions.

C. Motivation: Introduce and integrate clean research data which will improve user insights, abide by federal compliance requirements using better data management.

The primary objective of this database project is to bolster various aspects of data management, such as ensuring data completeness, reducing duplication, enhancing accuracy, maintaining conformity, ensuring consistency, and upholding data integrity. One specific focus is on enhancing the quality of regulatory data stored within a proposed regulatory information management table.

The overarching aim of the improvement points is to develop a robust system for conducting data quality checks across data sources, management services, and the company's core systems responsible for handling data critical for upkeeping regulatory compliance which will extend to ensuring ISO standards compliance within the pharmaceutical industry.

D. Potential Benefits: R&D productivity boost, improved compliance, and risk management.

Implementing a robust database solution in a pharmaceutical firm offers numerous benefits to stakeholders and potentially the industry as a whole.

Improved compliance is a key advantage. A well-designed database solution ensures that regulatory requirements are met consistently, reducing the risk of non-compliance penalties and regulatory issues. This not only protects the firm's reputation but also instills trust among regulatory agencies and consumers.

Overall, the benefits of implementing a robust database solution in the pharmaceutical and biotech industries include improved data integrity, enhanced regulatory compliance, reduced risks, and increased efficiency in managing clinical trial data and regulatory requirements. The concerns surrounding data consistency across sources would eliminate various data gaps that can create delays in the firm's objectives.

E. Potential Users: R&D scientists, Product managers, regulatory affairs specialists, marketing and sales teams, healthcare providers.

Roster of users that can contribute to or benefit from the database solutions:

R&D Scientists: R&D scientists can contribute to the database by inputting and analyzing experimental data, conducting data-driven research, and collaborating with other teams to develop new drugs and treatments. Access to a centralized

database enables R&D scientists to easily retrieve and share research findings, track experimental results, and identify patterns or trends to drive innovation and enhance decision-making.

Product Managers: Product managers can contribute by updating product information, monitoring market trends, and aligning product development strategies with market demand. The database provides product managers with real-time insights into market dynamics, customer feedback, and competitor analysis, facilitating informed product decisions and effective product lifecycle management.

Regulatory Affairs Specialists: Regulatory affairs specialists can contribute by ensuring data compliance with regulatory standards, maintaining accurate documentation, and managing regulatory submissions. The database streamlines regulatory processes, facilitates regulatory tracking and reporting, and helps in timely compliance with regulatory changes, reducing risks of noncompliance and ensuring product approvals.

Marketing and Sales Teams: Marketing and sales teams can contribute by accessing customer data, analyzing market trends, and developing targeted marketing campaigns. The database provides insights into customer preferences, buying behavior, and market segmentation, enabling marketing and sales teams to tailor their strategies, optimize lead generation, and increase sales effectiveness.

Healthcare Providers: Healthcare providers can contribute by inputting patient data, accessing clinical trial results, and collaborating with researchers for evidence-based medicine. The database facilitates seamless data sharing between healthcare providers, researchers, and patients, leading to improved patient care, personalized treatments, and better clinical outcomes.

SECTION 2; BUSINESS RULES & USER REQUIREMENTS

A. Business Activities

Outlining key business activities and requirements for the database system we need developed; core entities include patients, clinics/hospitals, medications, and prescriptions. Business activities must also take into account regulatory compliance and risk management.

In terms of relationships, patients can have multiple prescriptions, each prescription is associated with one patient, one clinic/hospital, and one medication. Clinics/hospitals can issue multiple prescriptions, and medications can be prescribed in multiple prescriptions. Each prescription is uniquely identified, and referential integrity constraints are essential to ensure data accuracy and validity.

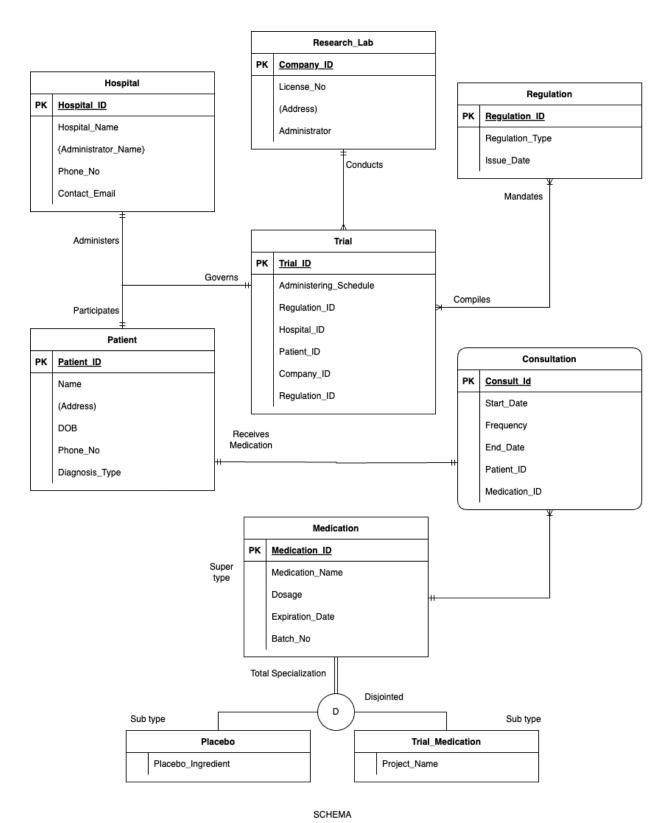
Database must support tracking billing information for each prescription, including total cost based on medication price per unit and quantity prescribed. The system should enforce business rules such as unique identifiers, relationship constraints, and accurate recording of prescription details. Additionally, the database should facilitate regulatory compliance by storing necessary documentation, ensuring data security and privacy, and generating reports for regulatory audits. This comprehensive database solution will streamline our operations, improve patient care, ensure regulatory compliance, and mitigate risks effectively.

B. User Requirements

Our core entities include patients, medications, outside organizations, and regulatory inputs and prescriptions. Each patient has a unique identifier (Patient_ID) along with attributes like Name, Address, Date_of_Birth, Gender, and Phone_Number. Clinics/hospitals are also uniquely identified (Clinic_ID) and have attributes such as Clinic_Name, Address, Contact_Number, and Email Address.

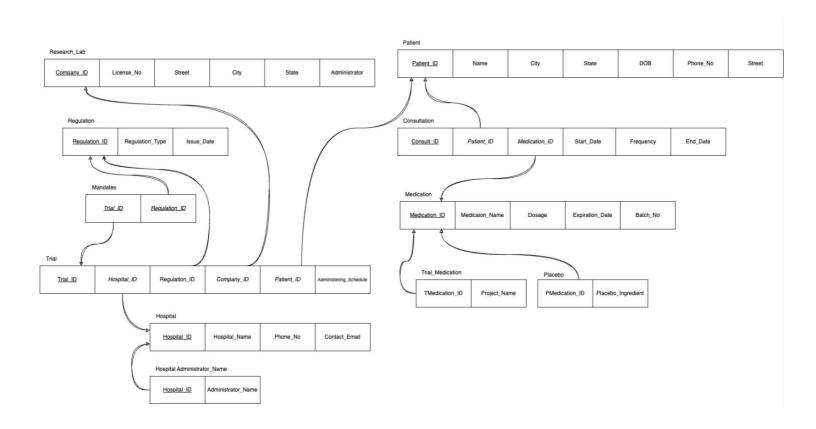
Medications are a vital entity with a unique identifier (Medication_ID) and attributes like Medication_Name, Dosage, Expiry_Date, Manufacturer, and Price_Per_Unit. Prescriptions are the link between patients, clinics, medications, and include attributes such as Prescription_ID, Patient_ID (referencing patients), Medication_ID (referencing medications), Clinic_ID (referencing clinics), Prescribing_Physician, Prescription_Date, and Quantity.

Outside organization details regarding Clinic info or Hospital info, and Regulatory Management informationation should be included for compliance elements SECTION 3; ENHANCED ENTITY RELATION DIAGRAM



Project_Deliverable_3

FULL VIEW (Please Zoom In)



Project_Deliverable_3

SECTION 5; SQL CODES TO CREATE TABLES AND INSERT RECORDS

TABLES

```
RESEARCH LAB
     CREATE TABLE research lab (
                            VARCHAR(45) NOT NULL,
      company id
      license no
                      VARCHAR(60)
      street
                            VARCHAR(60)
                            VARCHAR(60)
      city
      state
                            VARCHAR(60)
      research admin VARCHAR(24)
      CONSTRAINT researchlab_pk PRIMARY KEY (company id));
REGULATION
     CREATE TABLE regulation (
      regulation id
                            VARCHAR(45) NOT NULL
      regulation type
                            VARCHAR(60)
                            DATE
      issue date
      CONSTRAINT regulation pk PRIMARY KEY (regulation id));
MEDICAL TRIAL
     CREATE TABLE trial (
                            VARCHAR(45) NOT NULL
      trial id
      hospital id
                      VARCHAR(45) NOT NULL
      regulation id
                      VARCHAR(45) NOT NULL
      company id
                            VARCHAR(45) NOT NULL
      patient id
                      VARCHAR(45) NOT NULL
      administering scheddule VARCHAR(45)
      CONSTRAINT trial pk PRIMARY KEY (trial id),
      CONSTRAINT trial fk1 FOREIGN KEY (hospital id) REFERENCES hospital
     (hospital id),
      CONSTRAINT trial fk2 FOREIGN KEY (regulation id) REFERENCES
     regulation (regulation id),
      CONSTRAINT trial fk3 FOREIGN KEY (company id) REFERENCES
     research lab (company id),
      CONSTRAINT trial fk4 FOREIGN KEY (patient id) REFERENCES patient
     (patient id));
MANDATES
     CREATE TABLE mandates (
      trial id
                            VARCHAR(45) NOT NULL,
      regulation id
                      VARCHAR(45)
                                        NOT NULL
      CONSTRAINT mandates pk PRIMARY KEY (trial_id, regulation_id),
      CONSTRAINT mandates fk1 FOREIGN KEY (trial id) REFERENCES trial
     (trial id),
```

```
CONSTRAINT mandates fk2 FOREIGN KEY (regulation id) REFERENCES
     regulation (regulation id));
HOSPITAL
     CREATE TABLE hospital (
                      VARCHAR(45) NOT NULL,
      hospital id
      hospital name
                           VARCHAR(45)
      phone no
                           VARCHAR(11)
      contact email
                           VARCHAR(45)
      CONSTRAINT hospital pk PRIMARY KEY (hospital id));
HOSPITAL ADMIN
     CREATE TABLE hospital admin name (
      admin id VARCHAR(45) NOT NULL,
      hospital id VARCHAR(45) NOT NULL,
      administrator name VARCHAR(45),
      CONSTRAINT hospital admin name pk PRIMARY KEY (admin id),
      CONSTRAINT hospital admin name fk1 FOREIGN KEY (hospital id)
     REFERENCES hospital (hospital id));
PATIENT
     CREATE TABLE patient (
      patient id
                      VARCHAR(45) NOT NULL
                           VARCHAR(60)
      patient name
                           VARCHAR(60)
      street
      city
                           VARCHAR(45)
                           VARCHAR(10)
      state
      dob
                           DATE
                           VARCHAR(11)
      phone no
      CONSTRAINT patient pk PRIMARY KEY (patient id));
MEDICATION
     CREATE TABLE medication (
      medication id
                           VARCHAR(45) NOT NULL,
      medication name VARCHAR(60)
      dosage
                           VARCHAR(45)
      expiration date DATE
                           INTEGER
      batch no
      CONSTRAINT medication pk PRIMARY KEY (medication id));
```

TRIAL MEDICATION

```
CREATE TABLE trial medication (
```

medication_id VARCHAR(45) NOT NULL,

project name VARCHAR(60)

CONSTRAINT trial medication pk PRIMARY KEY (medication id),

```
CONSTRAINT trial_medication_fk1 FOREIGN KEY (medication_id) REFERENCES medication (medication id));
```

PLACEBO

```
CREATE TABLE placebo (
medication_id VARCHAR(45) NOT NULL,
placebo_ingredient VARCHAR(60) ,
CONSTRAINT placebo_pk PRIMARY KEY (medication_id),
CONSTRAINT placebo_fk2 FOREIGN KEY (medication_id) REFERENCES
medication (medication_id));
```

CONSULTATION

```
CREATE TABLE consultation (
                 VARCHAR(45) NOT NULL
 consult id
 patient id
                 VARCHAR(45)
                                   NOT NULL
 medication id
                       VARCHAR(45) NOT NULL,
 start date
                 DATE
 end date
                       DATE
frequency
                       VARCHAR(45)
 CONSTRAINT consultation pk PRIMARY KEY (consult id),
 CONSTRAINT consultation fk1 FOREIGN KEY (patient id) REFERENCES
patient (patient id),
 CONSTRAINT consultation fk2 FOREIGN KEY (medication id) REFERENCES
medication (medication id));
```

VALUES

PATIENTS

INSERT INTO patient (patient_id, patient_name, street, city, state, dob, phone_no) VALUES ('P001', 'Homer Simpson', '742 Evergreen Terrace', 'Springfield', 'IL', '1956-05-12', '3125550001');

INSERT INTO patient (patient_id, patient_name, street, city, state, dob, phone_no) VALUES ('P002', 'Marge Simpson', '742 Evergreen Terrace', 'Springfield', 'IL', '1956-10-01', '3125550002');

INSERT INTO patient (patient_id, patient_name, street, city, state, dob, phone_no) VALUES ('P003', 'Bart Simpson', '742 Evergreen Terrace', 'Springfield', 'IL', '1980-04-01', '3125550003');

INSERT INTO patient (patient_id, patient_name, street, city, state, dob, phone_no) VALUES ('P004', 'Lisa Simpson', '742 Evergreen Terrace', 'Springfield', 'IL', '1982-05-09', '3125550004');

INSERT INTO patient (patient_id, patient_name, street, city, state, dob, phone_no) VALUES ('P005', 'Maggie Simpson', '742 Evergreen Terrace', 'Springfield', 'IL', '1989-01-12', '3125550005');

INSERT INTO patient (patient id, patient name, street, city, state, dob, phone no)

VALUES ('P006', 'Ned Flanders', '744 Evergreen Terrace', 'Springfield', 'IL', '1952-03-01', '3125550006');

INSERT INTO patient (patient_id, patient_name, street, city, state, dob, phone_no)

VALUES ('P007', 'Montgomery Burns', '1000 Mammon Lane', 'Springfield', 'IL', '1890-09-15', '3125550007');

INSERT INTO patient (patient_id, patient_name, street, city, state, dob, phone_no) VALUES ('P008', 'Waylon Smithers', '1000 Mammon Lane', 'Springfield', 'IL', '1964-07-25', '3125550008');

MEDICATIONS

INSERT INTO medication (medication_id, medication_name, dosage, expiration_date, batch_no)

VALUES ('MED001', 'Amoxicillin', '500mg', '2025-12-31', 1001);

INSERT INTO medication (medication_id, medication_name, dosage, expiration_date, batch_no)

VALUES ('MED002', 'lbuprofen', '200mg', '2024-08-15', 1002);

INSERT INTO medication (medication_id, medication_name, dosage, expiration_date, batch_no)

VALUES ('MED003', 'Acetaminophen', '500mg', '2025-05-20', 1003);

INSERT INTO medication (medication_id, medication_name, dosage, expiration_date, batch_no)

VALUES ('MED004', 'Paracetamol', '500mg', '2025-10-30', 1004);

INSERT INTO medication (medication_id, medication_name, dosage, expiration_date, batch_no)

VALUES ('MED005', 'Loratadine', '10mg', '2025-09-15', 1005);

TRIAL MEDICATIONS

INSERT INTO trial_medication (medication_id, project_name)

VALUES ('MED001', 'Project Alpha');

INSERT INTO trial_medication (medication_id, project_name)

VALUES ('MED002', 'Project Beta');

PLACEBOS

INSERT INTO placebo (medication_id, placebo_ingredient)

VALUES ('MED003', 'Starch');

INSERT INTO placebo (medication_id, placebo_ingredient)

VALUES ('MED005', 'Cellulose');

CONSULTATIONS

INSERT INTO consultation (consult_id, patient_id, medication_id, start_date, end_date, frequency)

VALUES ('C001', 'P001', 'MED001', '2023-10-01', '2023-12-01', 'Twice daily');

INSERT INTO consultation (consult_id, patient_id, medication_id, start_date, end_date, frequency)

VALUES ('C002', 'P002', 'MED002', '2023-11-15', '2024-01-15', 'Once daily');

```
INSERT INTO consultation (consult id, patient id, medication id, start date, end date,
frequency)
VALUES ('C003', 'P003', 'MED003', '2023-09-20', '2023-11-20', 'Three times a week');
INSERT INTO consultation (consult id, patient id, medication id, start date, end date,
frequency)
VALUES ('C004', 'P004', 'MED004', '2023-10-05', '2023-12-05', 'Once a week');
REGULATIONS
INSERT INTO regulation (regulation id, regulation type, issue date)
VALUES ('0000-R001', 'Federal Regulation', '2022-04-28');
INSERT INTO regulation (regulation id, regulation type, issue date)
VALUES ('1111-R002', 'State Regulation', '2023-01-15');
INSERT INTO regulation (regulation id, regulation type, issue date)
VALUES ('9999-R003', 'Local Ordinance', '2021-11-07');
INSERT INTO regulation (regulation id, regulation type, issue date)
VALUES ('0000-R004', 'Federal Regulation', '2022-08-19');
INSERT INTO regulation (regulation id, regulation type, issue date)
VALUES ('1111-R005', 'State Regulation', '2020-05-22');
RESEARCH LABS
INSERT INTO research lab (company id, license no, street, city, state,
research admin)
VALUES ('C001', 'LIC78945', '123 Elm St', 'Springfield', 'Illinois', 'Sheldon Cooper');
INSERT INTO research lab (company id, license no, street, city, state,
research admin)
VALUES ('C002', 'LIC12356', '456 Maple Ave', 'Centerville', 'Ohio', 'Howard Walowitz');
INSERT INTO research lab (company id, license no, street, city, state,
research admin)
VALUES ('C003', 'LIC98321', '789 Oak Blvd', 'Riverside', 'California', 'Amy Farhafowler');
INSERT INTO research lab (company id, license no, street, city, state,
research admin)
VALUES ('C004', 'LIC56231', '101 Pine Road', 'Lakeview', 'Texas', 'Penny Hoffsteder');
INSERT INTO research lab (company id, license no, street, city, state,
research admin)
VALUES ('C005', 'LIC20485', '202 Birch Lane', 'Hilltown', 'Florida', 'Stuart Bloom');
TRIALS
INSERT INTO trial (trial id, hospital id, regulation id, company id, patient id,
administering scheddule)
VALUES ('T001', 'H001', '0000-R001', 'C001', 'P001', 'Daily');
```

INSERT INTO trial (trial_id, hospital_id, regulation_id, company_id, patient_id, administering_scheddule)

VALUES ('T002', 'H002', '0000-R004', 'C002', 'P002', 'Weekly');

MANDATES

INSERT INTO mandates (trial_id, regulation_id)

VALUES ('T001', '0000-R001'); INSERT INTO mandates (trial_id, regulation_id) VALUES ('T002', '0000-R004');

HOSPITALS

INSERT INTO hospital (hospital_id, hospital_name, phone_no, contact_email) VALUES ('H001', 'Saint Mary"s Hospital', '1234567890', 'contact@smhospital.com'); INSERT INTO hospital (hospital_id, hospital_name, phone_no, contact_email) VALUES ('H002', 'City Health Clinic', '0987654321', 'info@cityclinic.com'); INSERT INTO hospital (hospital_id, hospital_name, phone_no, contact_email) VALUES ('H003', 'General Hospital', '1122334455', 'admin@generalhospital.com');

HOSPITAL ADMINS

INSERT INTO hospital_admin_name (admin_id, hospital_id, administrator_name) VALUES ('A001', 'H001', 'Dr. Julius Hibbert');

INSERT INTO hospital_admin_name (admin_id, hospital_id, administrator_name) VALUES ('A002', 'H002', 'Dr. Nick Riviera');

INSERT INTO hospital_admin_name (admin_id, hospital_id, administrator_name) VALUES ('A003', 'H003', 'Dr. Algernop Krieger');

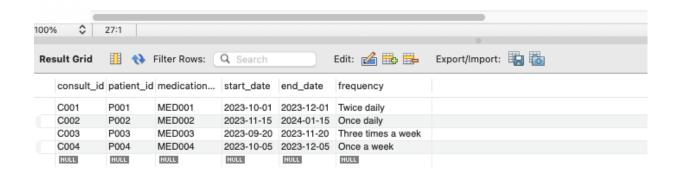
INSERT INTO hospital_admin_name (admin_id, hospital_id, administrator_name) VALUES ('A004', 'H004', 'Dr. Joan Watson');

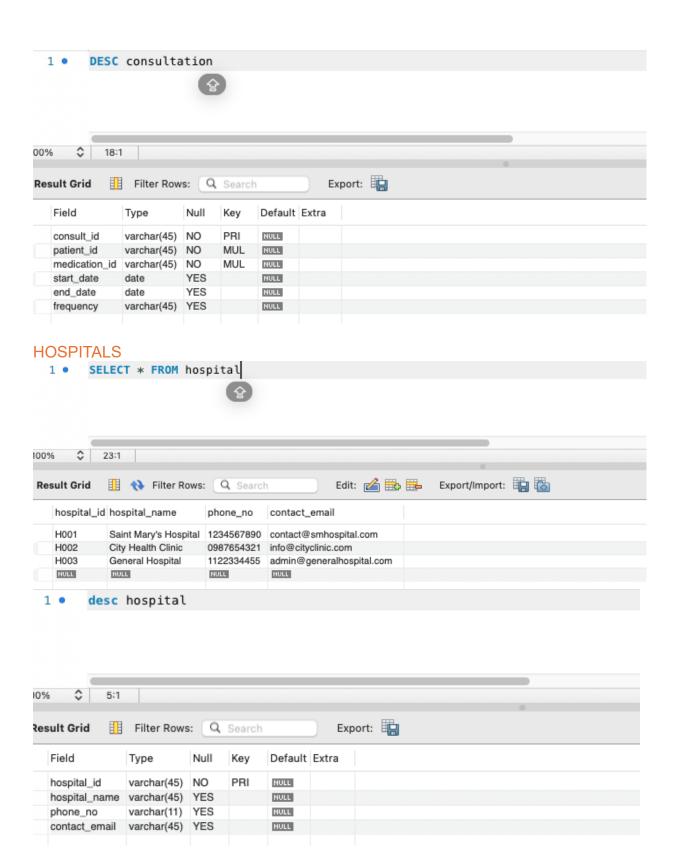
INSERT INTO hospital_admin_name (admin_id, hospital_id, administrator_name) VALUES ('A005', 'H005', 'Dr. Meredith Grey');

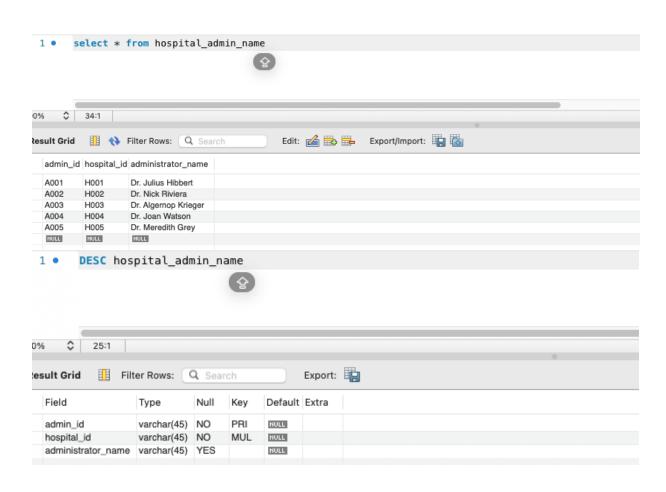
SECTION 6; ALL TABLES AND RECORDS USING DESC & SELECT COMMANDS

CONSULTATIONS

1 • select * from consultation



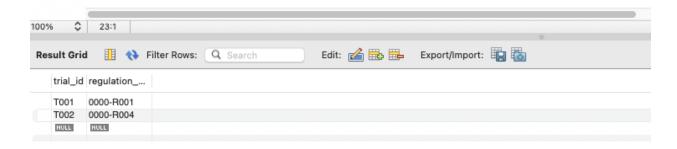


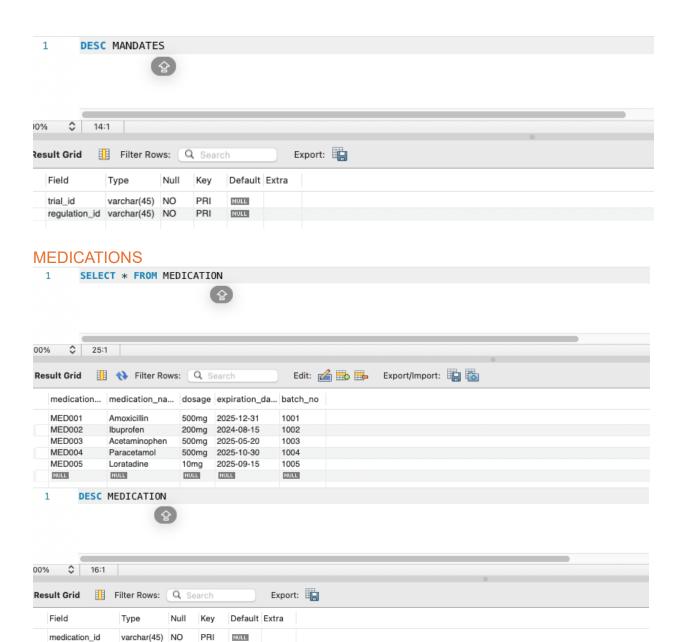


MANDATES

1 SELECT * FROM MANDATES







NULL

NULL

NULL

NULL

medication_name varchar(60) YES

varchar(45) YES

YES

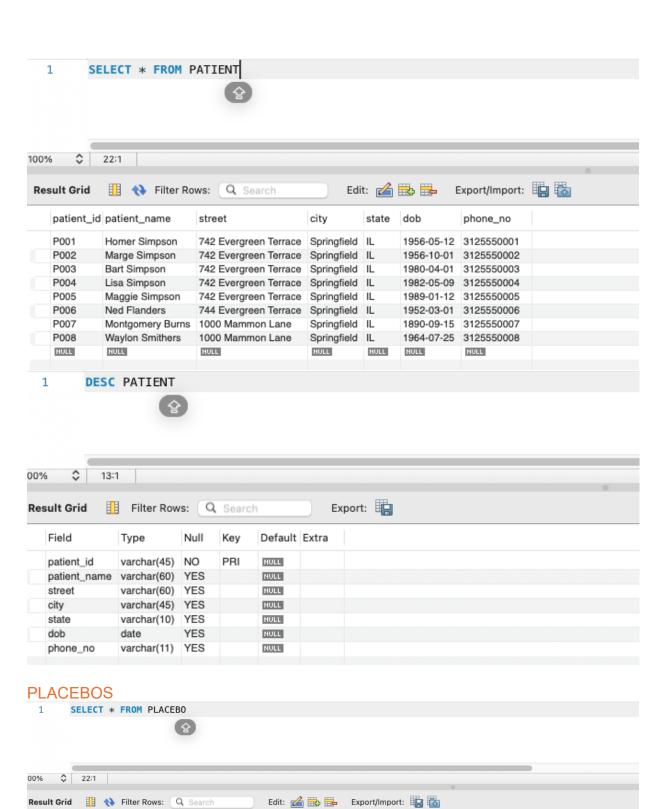
YES

date

dosage

batch_no

expiration_date



medication... placebo_ingredi...

Starch

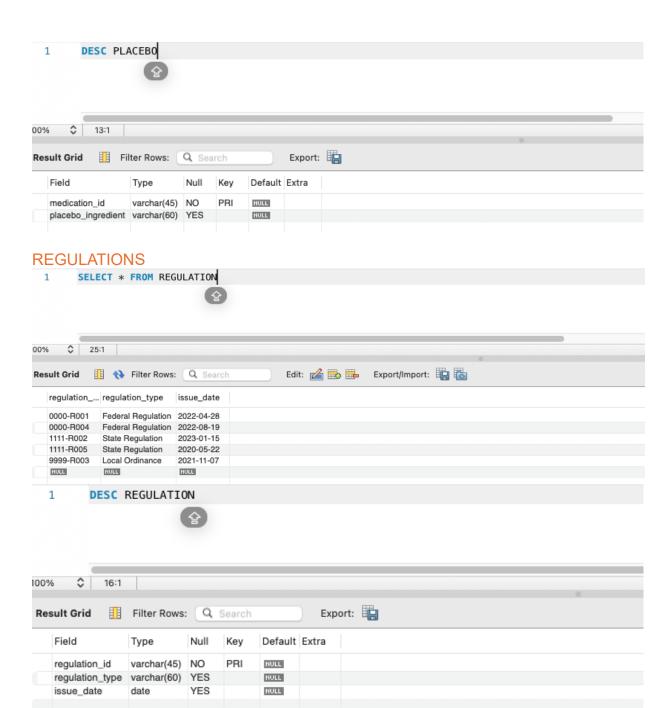
NULL

Cellulose

MED003

MED005

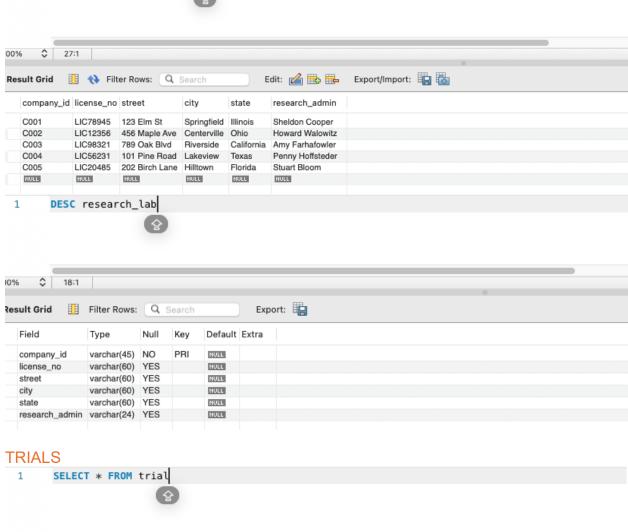
NULL

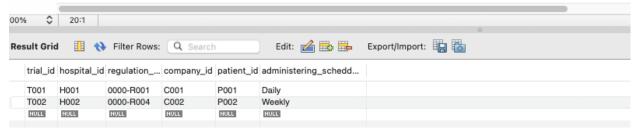


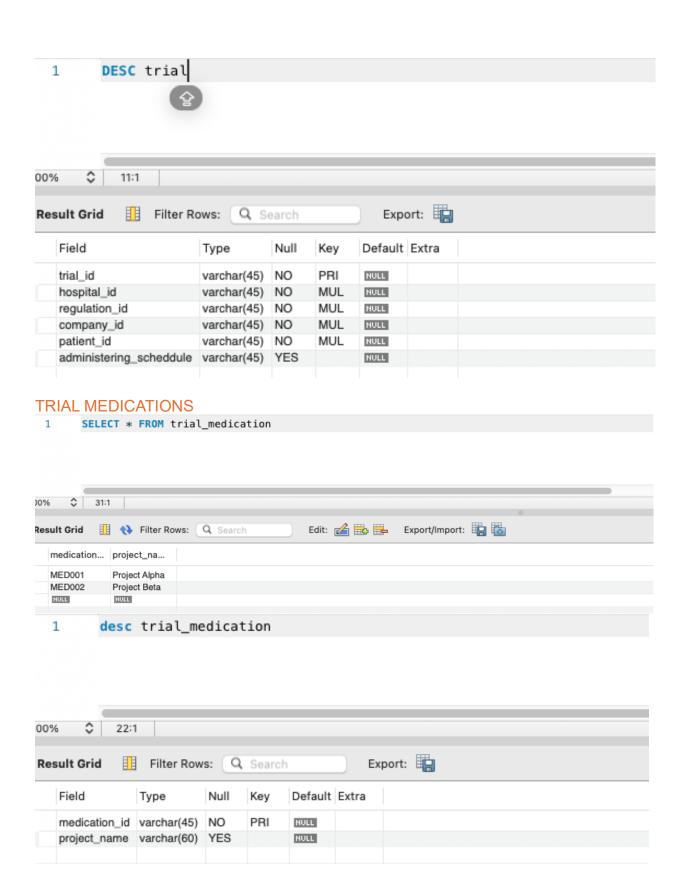
RESEARCH LABS

1 SELECT * FROM research_lab

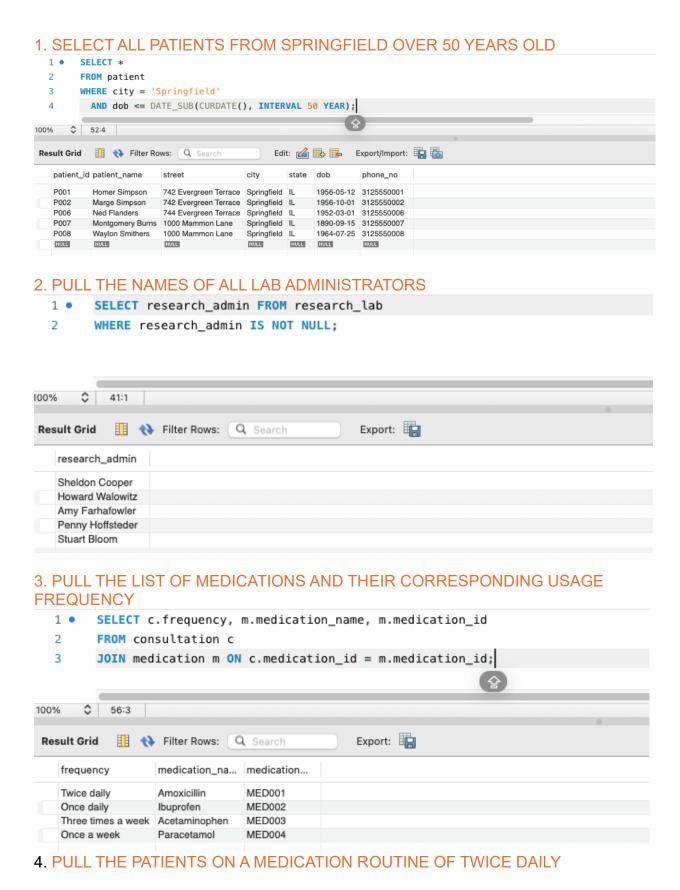








SECTION 7; SQL QUERIES TESTED WITH MYSQL





Section 1a – 1e Reference Materials:

https://www.striped-giraffe.com/en/blog/how-the-pharmaceutical-industry-can-meet-the-challenges-of-data-quality-management/

https://www.biopharmadive.com/spons/addressing-the-challenges-of-data-management-for-pharmaceutical-and-biotech/573858/

https://www2.deloitte.com/us/en/insights/industry/technology/challenges-in-data-management.html

https://www.acdlabs.com/blog/data-management-and-drug-quality-in-pharmaceutical-manufacturing/

https://www.technologynetworks.com/informatics/articles/data-integrity-what-are-some-of-the-key-issues-314165