TERM PROJECT PROPOSAL

INFO 5707.401: Data Modelling for Information Professionals

University of North Texas, Department of Information Science

Group 3

Team Members:

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Proposed Project Topics:

1. **Electronic Health Records (EHR) Management System:**

   Proposed by – **Varsha Sane**

The Electronic Health Records (EHR) Management System is a tool which helps us to organize patients appointment, doctors details and medical records. It also helps in handling bills, also keeps tracks on patients visit and stores important of medications and health history. It can also create which shows the income summaries, how well doctors are doing and review of patients medical history.

2. **Medical Research and Clinical Trails Management Systems**:

   Proposed by – **Sai Shivani Parimi**

A clinical trial management system for medical research keeps track of investigators, trial subjects, drugs or treatments under investigation, and outcomes. The database is also capable of managing participant consent forms, tracking adverse events, and providing trial progress reports.

3. **Dental Clinic Management System:**

Proposed by – **Sunitha Byrapaka**

A dental clinic management system that keeps track of patient visits, dental operations, and inventory (supplies used in dental treatments). This system can manage payments and treatment records in addition to producing data on patient history, dentist productivity, and clinic performance.

4. **Public Health Data and Disease Tracking System**

Proposed by **– Ria Singh**

A system that keeps track of diseases, outbreaks, and patient details at a state or country level. It stores information about patients, medical staffs, treatments. Reports states how diseases are spreading or how effective treatments are.

5. **Medical Billing and Insurance Claims System**

Proposed by – **Pravallika Gummadivelli**

A medical billing system that manages insurance claims and procedure charges. It also helps in tracking claims sent to insurance companies, patient expenses and the status of those claims. It can also monitors payments and generate reports on unpaid bills
and denied claims.

Proposed Title

MEDICAL RESEARCH AND CLINICAL TRIALS MANAGEMENT SYSTEM

Objective:

The primary objective of our database system is to support and streamline clinical trial management in the medical field. Our database system will be designed to manage and store subject data, clinical trial protocols, results, and regulatory documents (HIPAA, GDPR). It will help us to maintain interactions between various people working with the data such as researchers, doctors, and clinical data managers.

1. Our database system ensures secure storage, confidentiality, and access control for patient data, adhering to regulatory standards.
2. This system provides a real-time monitoring and tracking of trial phases, patient progress, and protocol adherence.
3. This system maintains secure, accessible consent records with audit trails for regulatory compliance.
4. This system enables oversight functionalities for principal investigator to monitor and manage trial activities effectively.
5. Record and link test results to patient data, enabling seamless integration with the clinical trial timeline.
6. This system safeguards all regulatory documents with secure access, version control, and audit capabilities.
7. It allows detailed tracking of funding sources, budgets, and expenditures for transparency and financial compliance.
8. This system implements scheduling tools and notifications to ensure timely patient follow-ups and adherence to protocol timelines**.**
9. It ensures a secure and transparent randomization process, linking patient groups with trial outcomes.

10. It tracks investigational products' usage, inventory, and safety records, ensuring compliance with trial requirements and regulatory standards (like drugs used in clinical trails)

Scope:

The scope of the "Medical Research and Clinical Trail Management System" project:

1. Organizations like Research Institutions, Universities, Pharmaceutical and Biotechnology companies, Regulatory Agencies (FDA), Hospitals and Healthcare providers, the Medical Device Industry Public Health Organizations, and other industries that need clinical trial data for making any medical devices can use our database.
2. This system will keep track of complete patient data, such as demographics, medical history, contact details, and clinical trial enrollment information. This helps in patient analysis, progress tracking, and eligibility screening.
3. It can also be used to store real-time data that is being generated by the monitoring devices that are worn by subjects who stay far from the site.
4. Also helps in maintaining patient consent forms, including digital links to consent papers, the date of signature, and the consent status. Researchers and regulatory reviewers can easily verify consent, which also guarantees ethical compliance.
5. With the help of this database efficient monitoring of each clinical trial can be done and helps in the administration of the trial.
6. Keeping track of all the principal investigator information helps us to connect each trial to its individual researcher which increases collaboration within the team and responsibility.
7. Storing laboratory test results allows test data easily available making it possible to analyze lab test results across trials and patients.
8. Using this database we can manage regulatory documents which is important for maintaining compliance and will confirm that the database aligns with the legal requirements like HIPPA.

9. Helps to track financial information so that transparency is maintained with the sponsors and guarantees efficient clinical research budget management.
10. The database that we create can be used by various teams within an organization such as the clinical operations team, finance team, QA team, CRA's (Clinical Research Associate)

User's Requirement:

1. Store and access demographic and health data of patients. Monitor the consent status, enrollment, and progress of each patient in the clinical trial. Safeguard patient privacy by implementing secure data storage and access controls.
2. Document every phase and protocol detail of the clinical study. Monitor the status of the trial, including start and end dates, current participants, and results. Facilitate the scheduling and oversight of trial phases and related procedures.
3. Keep signed consent forms along with time-stamped records to ensure compliance with regulations. Allow straightforward access to consent information for verifying participant comprehension and consent status. Offer electronic signature options and tracking capabilities as needed.
4. Gather comprehensive details regarding the principal investigator (PI) and their credentials. Monitor the PI's duties, site authorizations, and oversight tasks related to the study. Facilitate communication among the PI, research team, and data managers within the system.
5. Keep track of test types, their scheduled dates, outcomes, and relevant patient information. Enable the connection of test results to particular trial phases and patients for evaluation. Guarantee that laboratory data adheres to quality control regulations and works seamlessly with other patient information.
6. Safeguard important regulatory documents (such as HIPAA, GDPR consents, and ethics board approvals) securely. Implement version control and maintain audit trails for every document to monitor changes and approvals. Facilitate document retrieval functions for easy access during audits or inspections.

7. Monitor funding origins, their amounts, and how they are utilized throughout various trial stages. Facilitate oversight of budgets, covering costs associated with patient care, testing, and study activities. Preserve historical funding information and allocations for reporting and auditing needs.
8. Arrange patient appointments, examinations, and subsequent actions in accordance with the trial protocol. Deliver reminders and alerts to both patients and staff regarding forthcoming appointments. Facilitate flexible scheduling modifications as needed due to trial conditions or updates to the protocol.
9. Oversee the randomization procedure in accordance with trial specifications (such as double-blind or placebo-controlled methods). Monitor the allocation of patients to either treatment or control groups for further analysis. Keep randomization documentation secure and limited to access by authorized individuals only.
10. Document details about the investigational medication under evaluation. Monitor stock levels, documentation of administration, and reports of adverse events to ensure safety. Connect drug to individual patients and study stages for comprehensive analysis.

Choice of DBMS: MYSQL is an open-source tool that offers CRUD operations and MYSQL is a user-friendly software

Business Rules:

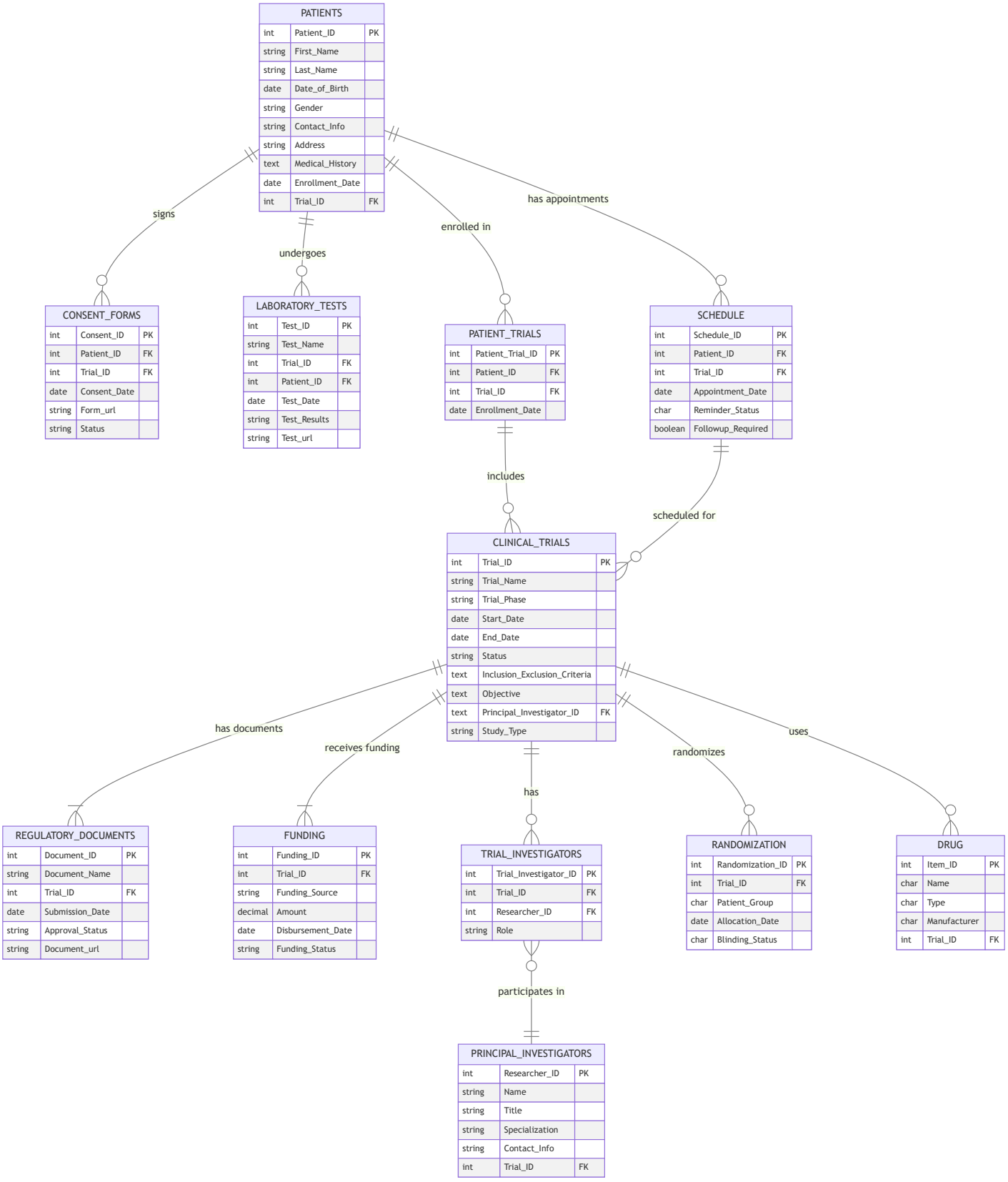
1. The relation between patient table and the Clinical_Trial table is many to many as each patient can enroll in multiple trials and each trial can have many patients. So, it is handled via a bridging table called PATIENT_TRIALS.
2. The relation between CLINICAL_TRIALS and PRINCIPAL_INVESTIGATORS is many to many as each trial can have multiple principal investigators and each investigator can be involved in multiple trials. So, it is handled via a bridging table called TRIAL_INVESTIGATORS.
3. A patient may be registered in the system without being enrolled in any clinical trial.

4. Each patient ID, trial ID, researcher ID, test ID, document ID, funding ID must be unique.
5. A clinical trial cannot proceed to the next phase unless the prior phase is completed, approved, and reviewed by the PI.
6. Each principal investigator may specialize in specific medical areas or disciplines.
7. A patient must sign a consent form to participate in a clinical trial.
8. A patient must sign a separate consent form for each clinical trial they are part of.
9. Each consent form is associated with only one patient and one clinical trial.
10. Consent forms must be stored securely with time-stamped records and must be accessible to auditors upon request.
11. A patient may not enroll in a clinical trial without signing a consent form
12. A patient may undergo multiple laboratory tests for different clinical trials.
13. Each laboratory test is associated with one patient and one clinical trial.
14. Each clinical trial must have one or more regulatory documents.
15. Each regulatory document is linked to one clinical trial and any trial must not begin until it is approved by the regulatory authority.
16. All regulatory documents must have version control enabled and an audit trail documenting who accessed or modified each document.
17. Each clinical trial may receive funding from multiple funding sources and the funding source must be documented with all the expenditures according to the approved budget.
18. Patient visits, tests, and procedures must follow the schedule outlined in the clinical trial protocol.
19. A patient can have multiple scheduled appointments, but each appointment is linked to only one patient.
20. A clinical trial can have multiple scheduled appointments, each associated with a specific patient, but each appointment links to only one clinical trial.
21. A clinical trial can have multiple randomization events, but each randomization event is associated with only one clinical trial.
22. A clinical trial can use multiple combinations of drugs, but each drug record tied to only one specific clinical trial.

Cardinality:

1. The minimum cardinality between PATIENTS and PATIENT_TRIALS is 0 (optional) on the PATIENT_TRIALS side because not every patient in the database will necessarily be enrolled in a clinical trial.
2. Cardinality is made optional on trial investigator side because not every principal investigator is required to be assigned to a trial and it is made mandatory on principal investigator side as every record in Trial_Investigator must have a linked PI.

3. Some clinical trials are just observatory trials without any tests being conducted. So, the minimum cardinality from patients to LABORATORY_TESTS is given as ‘0’.
4. Some patients might not pass the screening requirements so they may not sign the consent form or some may discontinue in between so for flexibility minimum cardinality is made 0.
5. Clinical trials will not start until the funding is finalized, so the minimum cardinality is made 1.
6. All clinical trials will have at least one regulator document as trials wouldn’t start without their approval so minimum cardinality is made 1.
7. The minimum cardinality between PATIENTS and SCHEDULE is 0 because some trials may not need any scheduling appointments or some patients might be placed on hold waiting for other phases of a trial in which that scheduled visit is not required.
8. The minimum cardinality between Clinical_Trial and SCHEDULE is 0 because a clinical trail may be paused or enrollment might not be started yet. So to maintain flexibility it is made 0.
9. The minimum cardinality between Clinical_Trial and randomization is 0 as not all the trials are randomized studies as some may be single arm studies also.
10. The minimum cardinality between Clinical_Trial and drug is 0 as some may be just observational trials or non-drug trails.


PATIENTS
int Patient_ID PK
string First_Name
string Last_Name
date Date_of_Birth
string Gender
string Contact_Info
string Address
text Medical_History
date Enrollment_Date
int Trial_ID FK
signs
undergoes
enrolled in
has appointments
CONSENT_FORMS
int Consent_ID PK
int Patient_ID FK
int Trial_ID FK
date Consent_Date
string Form_url
string Status
LABORATORY_TESTS
int Test_ID PK
string Test_Name
int Trial_ID FK
int Patient_ID FK
date Test_Date
string Test_Results
string Test_url
PATIENT_TRIALS
int Patient_Trial_ID PK
int Patient_ID FK
int Trial_ID FK
date Enrollment_Date
SCHEDULE
int Schedule_ID PK
int Patient_ID FK
int Trial_ID FK
date Appointment_Date
char Reminder_Status
boolean Followup_Required
includes
scheduled for
CLINICAL_TRIALS
int Trial_ID PK
string Trial_Name
string Trial_Phase
date Start_Date
date End_Date
string Status
text Inclusion_Exclusion_Criteria
text Objective
text Principal_Investigator_ID FK
string Study_Type
has documents
receives funding
has
randomizes
uses
REGULATORY_DOCUMENTS
int Document_ID PK
string Document_Name
int Trial_ID FK
date Submission_Date
string Approval_Status
string Document_url
FUNDING
int Funding_ID PK
int Trial_ID FK
string Funding_Source
decimal Amount
date Disbursement_Date
string Funding_Status
TRIAL_INVESTIGATORS
int Trial_Investigator_ID PK
int Trial_ID FK
int Researcher_ID FK
string Role
participates in
RANDOMIZATION
int Randomization_ID PK
int Trial_ID FK
char Patient_Group
date Allocation_Date
char Blinding_Status
DRUG
int Item_ID PK
char Name
char Type
char Manufacturer
int Trial_ID FK
PRINCIPAL_INVESTIGATORS
int Researcher_ID PK
string Name
string Title
string Specialization
string Contact_Info
int Trial_ID FK