CLINICAL TRAIL DATABASE

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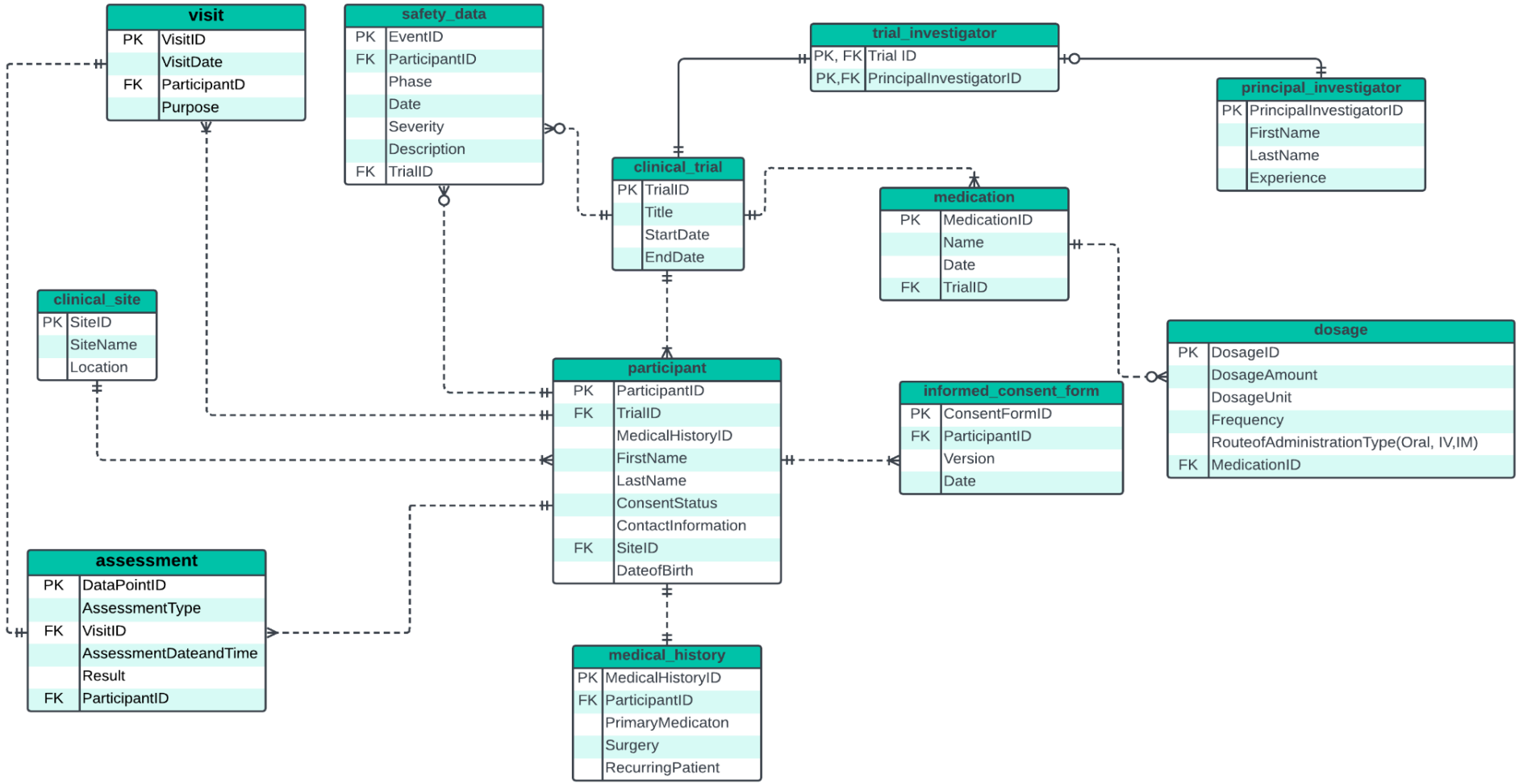
Entity Relationship Diagram (ERD):



Database Specifications: Purpose, Business Problems addressed, and Business Rules.

Database Purpose:

The purpose of this database is to support the management and documentation of clinical trials. It serves as a centralized repository for storing and organizing information related to clinical trials, participants, medical history, medication administration, safety data, and more. The database is designed to facilitate the efficient tracking and monitoring of various aspects of clinical trials, from participant enrollment to safety monitoring and progress tracking. It also helps in ensuring compliance with ethical and regulatory guidelines.

Business Problems Addressed:

1. **Participant Enrollment:** The database helps address the business problem of participant enrollment by providing information on how many participants are currently enrolled in each clinical trial. This data can help trial managers make informed decisions about recruitment strategies.
2. **Site Performance:** The database allows for the assessment of site performance in terms of participant recruitment. By tracking participant visits and assessments at different sites, it becomes possible to identify which sites are performing well and which ones are lagging, allowing for targeted interventions.
3. **Safety Monitoring:** The database enables safety monitoring by recording adverse events and safety data related to specific medications or interventions. This information helps in identifying safety concerns and managing them effectively.
4. **Progress Tracking:** It helps in tracking the progress of each clinical trial in terms of its timeline. This feature allows for the identification of delays or issues that may require attention, ensuring trials stay on schedule.
5. **Compliance:** The database ensures that all participants are properly informed and have given their consent to participate in the trials. It helps in monitoring compliance with ethical and regulatory guidelines, ensuring that trials are conducted ethically and legally.
6. **Resource Allocation:** By recording data on investigator medications and their distribution across ongoing trials, the database assists in effective resource allocation, ensuring that medications are available where needed.
7. **Outcome Analysis:** The database can provide preliminary results of each trial, allowing for early indications of treatment efficacy or safety concerns. This is crucial for making data-driven decisions about trial outcomes.
8. **Reporting and Documentation:** The database streamlines the generation of reports and documentation required for regulatory authorities, ethics committees, and sponsors, making the reporting process more efficient and reliable.

Business Rules:

1. One Principal Investigator must be assigned to only one Clinical Trial.
2. Each Participant may have only one Medical History.
3. Medications can have a varied amount of Doses since we will be giving placebo to a certain percentage of the population.
4. Participants can Visit many times to any of the clinics and an Assessment will be done on each Visit.

Design Requirements:

1. Use Crow's Foot Notation.
2. Specify the primary key fields in each table by specifying PK beside the fields.
3. Draw a line between the fields of each table to show the relationships between each table. This line should be pointed directly to the fields in each table that are used to form the relationship.
4. Specify which table is on the one side of the relationship by placing a one next to the field where the line starts.
5. Specify which table is on the many side of the relationship by placing a crow's feet symbol next to the field where the line ends.

Design Decisions:

Entity name	**Why entity included**	**Relation with other entities**
Clinical Trial	In a clinical trial database, the Clinical Trial entity serves as a central component for managing and documenting the details of the clinical trials being conducted. The purpose of the Clinical Trial entity is to provide a comprehensive record of each clinical trial, its characteristics, and its progress. The Clinical Trial entity contains essential information about each clinical trial including trialID, title, and the trial's dates.	This entity contains trial ID as the primary key which uniquely defines each clinical trial. Many participants from the Participant entity can take part in a single clinical trial and a clinical trial can have zero or many safety events. Also, a clinical Trial Entity should have at least one Principal Investigator to conduct the trial and this entity can have many Medications associated with each trial.
Principal Investigator	The Principal Investigator entity contains information about the investigator or physician responsible for overseeing the	This entity is linked to the Trial Investigator entity which links to the clinical trial entity which contains information on the clinical

	clinical trial.	trial. Here the Principal investigator ID is the primary key that uniquely defines each principal investigator.
Participant	This entity gives the details about each participant taking part in the clinical trial.	This entity is linked with the Medical History entity which specifies the details about the participant's medical history, the Saftey Data entity, Consent Form entity, Visit entity, Assessment entity and the Clinical Site entity which gives the details of the clinical sites.
Informed Consent form	This entity provides the consent information about the participant, any changes in the trial or experimentation are informed to the patient and a document is signed by the patient, this data is collected and stored in this table.	This entity is linked with the Participant entity.
Trial investigator	The Trial Investigator entity in a clinical trial database establishes a direct relationship between investigators and the clinical trials they are involved in.The entity often designates one or more investigators as Principal Investigators. These individuals typically play a leadership role in the trial and are responsible for the study's design, execution, and reporting.	This entity links trial investigators to specific clinical trials, identifying the principal investigators responsible for conducting or overseeing a particular trial.
Visit	This entity helps in tracking and managing the appointments or visits of participants in the clinical trial. It records when a participant is scheduled to come for various activities such as screenings, treatments, follow-ups, or other assessments.	This entity is linked with Assessment entity and the Participant entity.
Assessment	This entity is used to collect and record data related to the clinical trial. This data can include a wide range of measurements,	This entity links the Participant's assessment data on each visit to the corresponding Visit entity and Participant

	observations, and assessments, such as lab test results, questionnaire responses, physical examinations, or any other type of data relevant to the trial. Assessments are often performed during specific appointments or visits within the trial.	entity which helps in understanding when and where the assessment was conducted and to whom it was conducted.
Medication	The Medication entity stores detailed information about the medications or interventions used in the clinical trial. This includes the name of the medication, dosage, and dates. It is used to manage the various medications administered to trial participants as part of the clinical trial protocol.	This entity is linked directly to the clinical trial and dosage entity. For each medication, ensuring that participants receive the correct amount as per the trial protocol.
Dosage	Dosage information ensures that trial participants receive the correct amount of medication according to the study protocol. Accurate dosing is essential for the effectiveness of the treatment and for obtaining reliable trial results.	This entity is embedded with Medication entity to provide accurate dosage amount, unit, frequency, and route of administration.
Medical History	The Medical History entity captures a participant's comprehensive health profile, including their past and current medical conditions, medications, surgeries, and relevant medical events. At the beginning of a clinical trial, the medical history provides a baseline assessment of a participant's health.	This entity is related to the Participant entity to document a participant's health profile, assessing eligibility and risks.
Safety Data	This entity is included to capture and manage information related to safety events and adverse reactions occurring within clinical trials. It records essential details such as event ID, date, severity, description, participant ID, and phase. This information is crucial for monitoring participant safety, regulatory compliance, and overall the	This entity is associated with both Participant and Clinical Trial entities. These relationships are vital for tracking and managing safety events and adverse reactions within the context of clinical trials. Safety Data records are linked to individual participants and specific clinical trials, facilitating the attribution of safety data to

	assessment of a trial's safety profile.	participants and the categorization of safety events by trial.
Clinical Site	This entity is included to manage and organize information about the physical locations or sites where clinical trials are conducted. It plays a crucial role in clinical trial management by recording details about the various trial sites, such as their names and physical locations. This data helps in coordinating, scheduling, and ensuring proper site allocation for clinical trials.	This entity is related to the Participant entity. This relationship signifies that participants in clinical trials are often associated with specific clinical sites, such as hospitals or clinics. It allows for the tracking of which clinical site each participant is affiliated with, which is important for study coordination and understanding where participants are receiving treatment or participating in trials.