Law, Ethics, and Security Plan of Database Management System (DBMS)

for

Westlake Research Hospital Clinical Trial

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- *18-month double-blind clinical trial*

- *Current process of clinical trial data handling and processes are vulnerable and inefficient*

- *A database is required to secure and manage such data to uphold the integrity of the trial, adhere to HIPAA laws and allow accurate reproducibility of the trial results*

Getting Medicines to Patients:
The Clinical Trial Process

Inspired by **patients.**
Driven by **science.**

Conceptual Model

The conceptual model represents the data subject areas that the database will store.

We can see those subject areas in this slide, which includes the patients, their address, doctors, drugs, supervisors, appointments, recommendations, notes, medications, test results, symptoms and conditions.
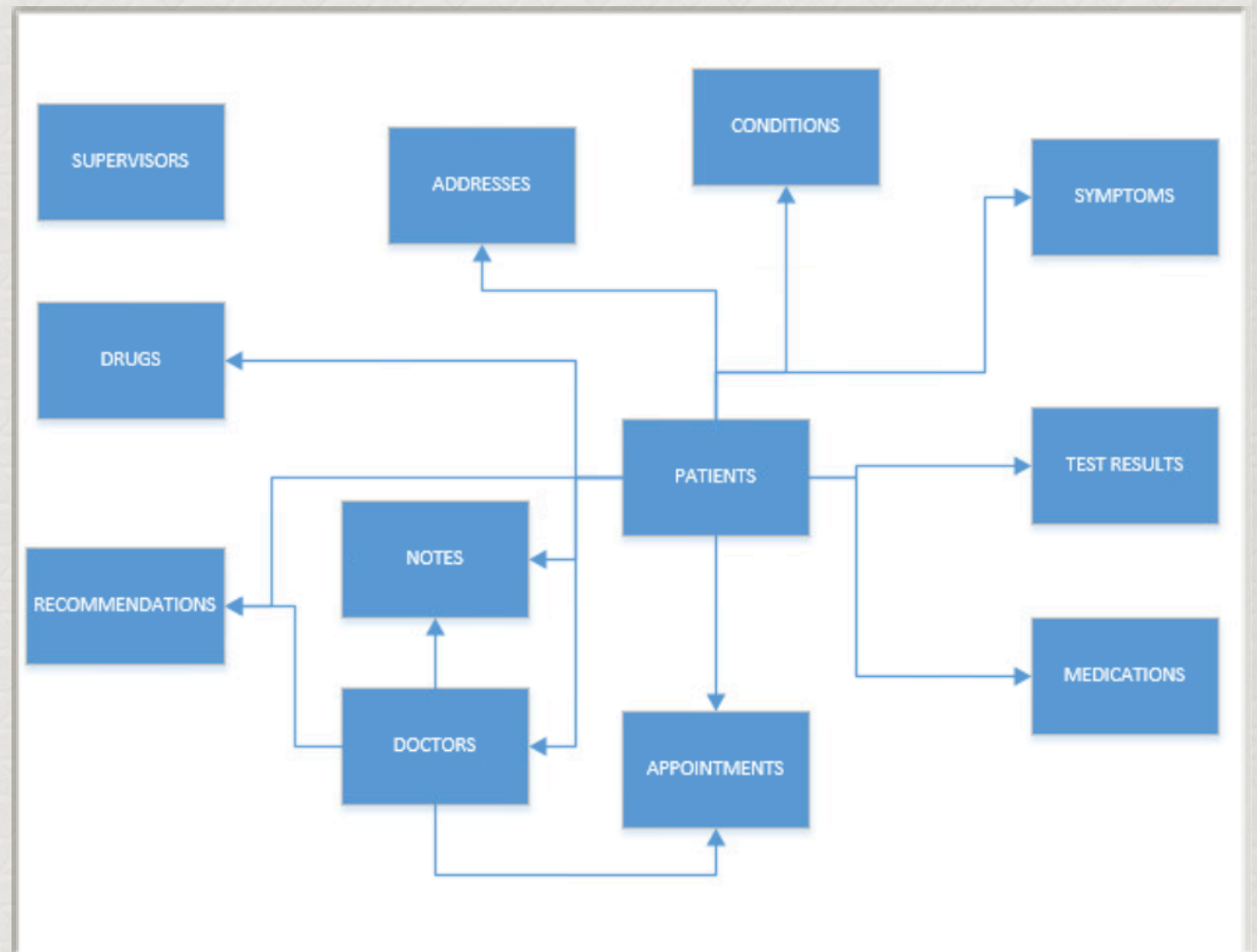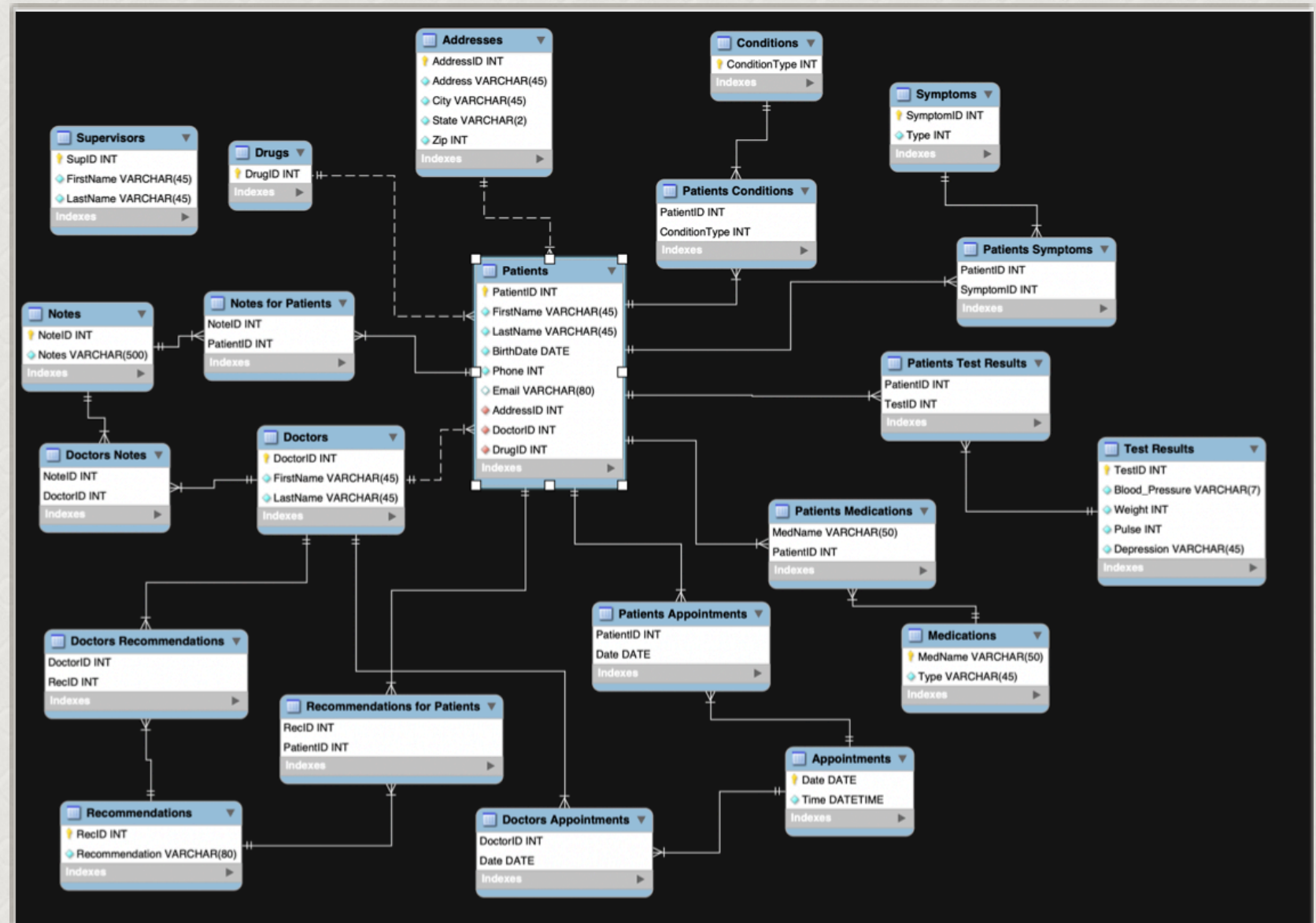
Logical Model

In this logical model, there are specific attributes for each entity.

*These attributes have specific names with detailed datatypes.*

In addition to this, the entity relationships have been developed, as instead of simple arrows, the relationship lines now display how these entities interact.

Physical Model

We can see all the tables, their attributes and the relevant relationship lines between tables.

With the physical model being the finalized design, with this construct, sample data can be given to the system to determine its operational effectiveness.
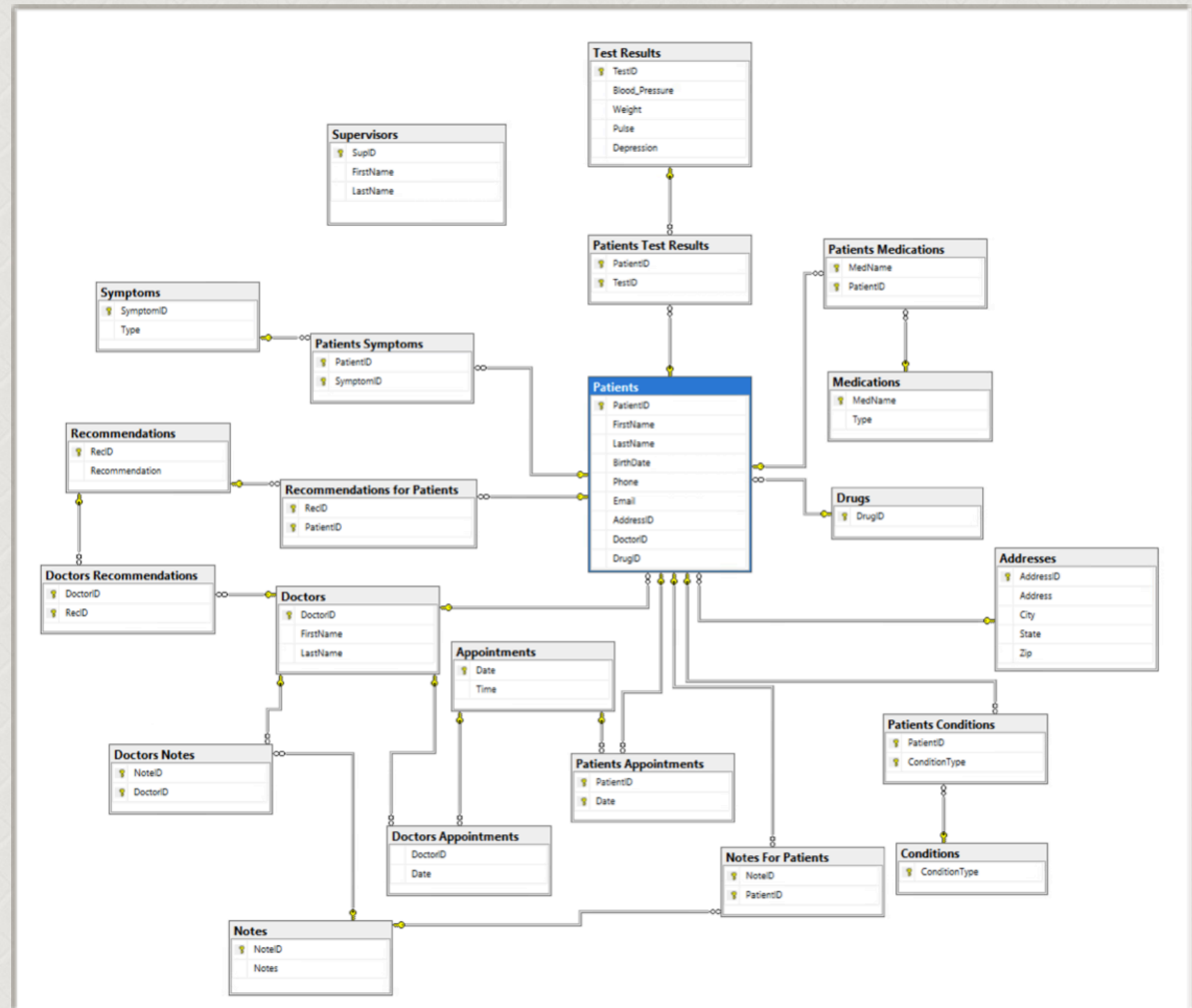
Database Management System (DBMS) Recommendation

- *Benefits of utilizing MSSQL include its' processing speed, performance throttling capabilities, which adjusts to incoming/outgoing loads, and its' unique ability to track changes made to the data and the "dynamic data masking, which ensures that only authorized individuals will see sensitive data" (Arsenault, 2017)*

- *MSSQL has the reliability, the performance measurements and security protocols that match specific needs for the Westlake Research Hospital Clinical Trial*

- *The clinical trial is an internal event with no requirement to deploy, which, in concern of cost, would eliminate the more expensive options. Additionally, in the event of system complications or development/implementation roadblocks, MSSQL has rich documentation and community assistance (Pijacek, 2019)*

Enterprise Data Model (EDM)

- *The Enterprise Data Model (EDM) is designed with domain specific characteristics that places emphasis on unbiased integration*

- *"The model can be thought of much like an architectural blueprint is to a building; providing a means of visualization, as well as a framework supporting planning, building and implementation of data systems" (Kendie, 2005)*

- *The EDM enables the identification of shareable and/or redundant data across functional and organizational boundaries, which unites, formalizes and represents the things important to an organization, such as data quality, consistency, accuracy and cross-functional extensibility (Kendie, 2005).*

Enterprise Subject Area Model (ESAM)

The ESAM lays out the foundational structure and the subjects that are critical to the current clinical trial implementation, as well as any future trial events.

This model will be the data system blueprint for all subsequent trial studies.
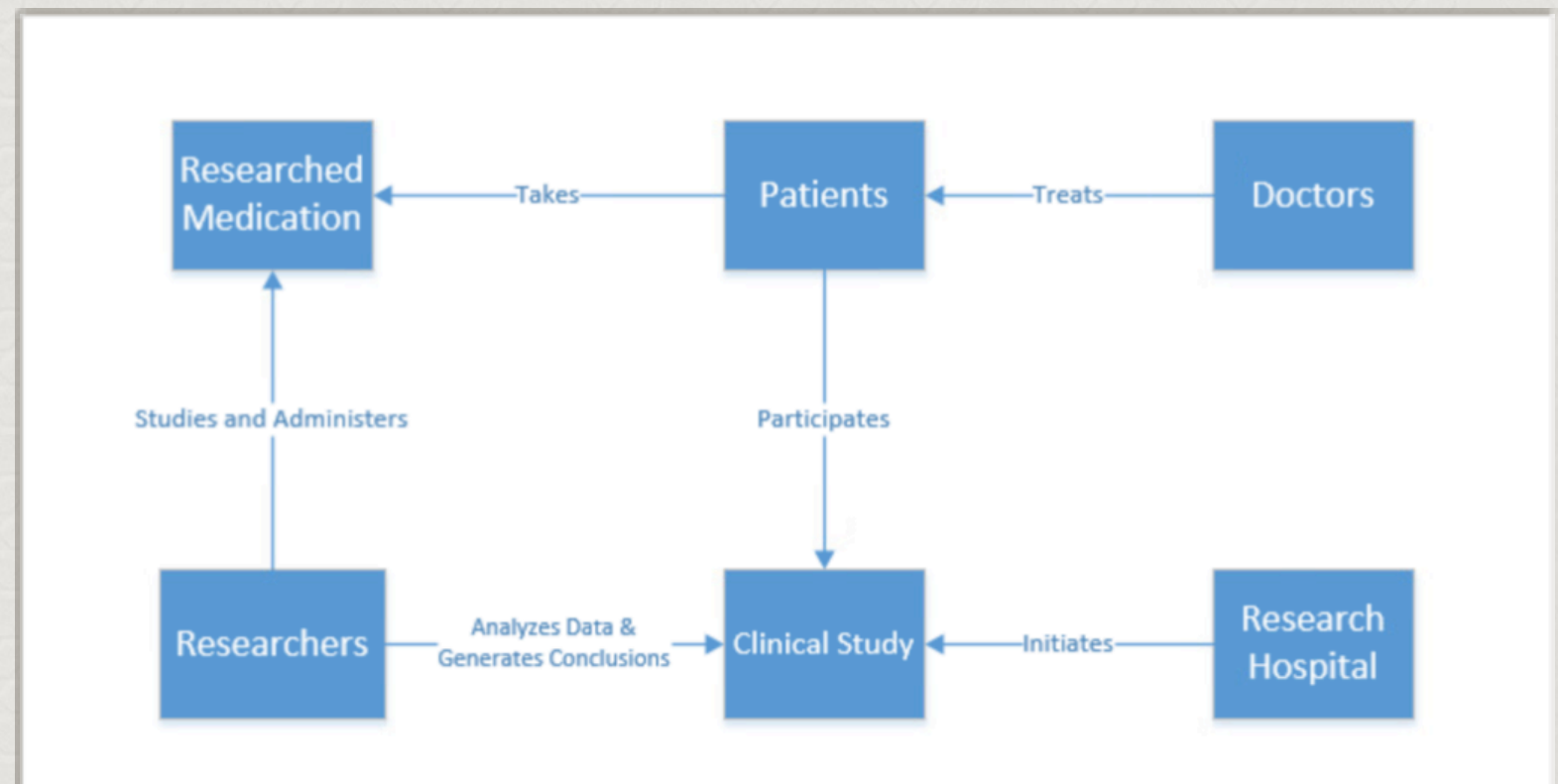
# Enterprise Conceptual Model (ECM)

The ECM establishes the identified subjects areas by incorporating high-level subject concept details and displays the nature of their relationships.
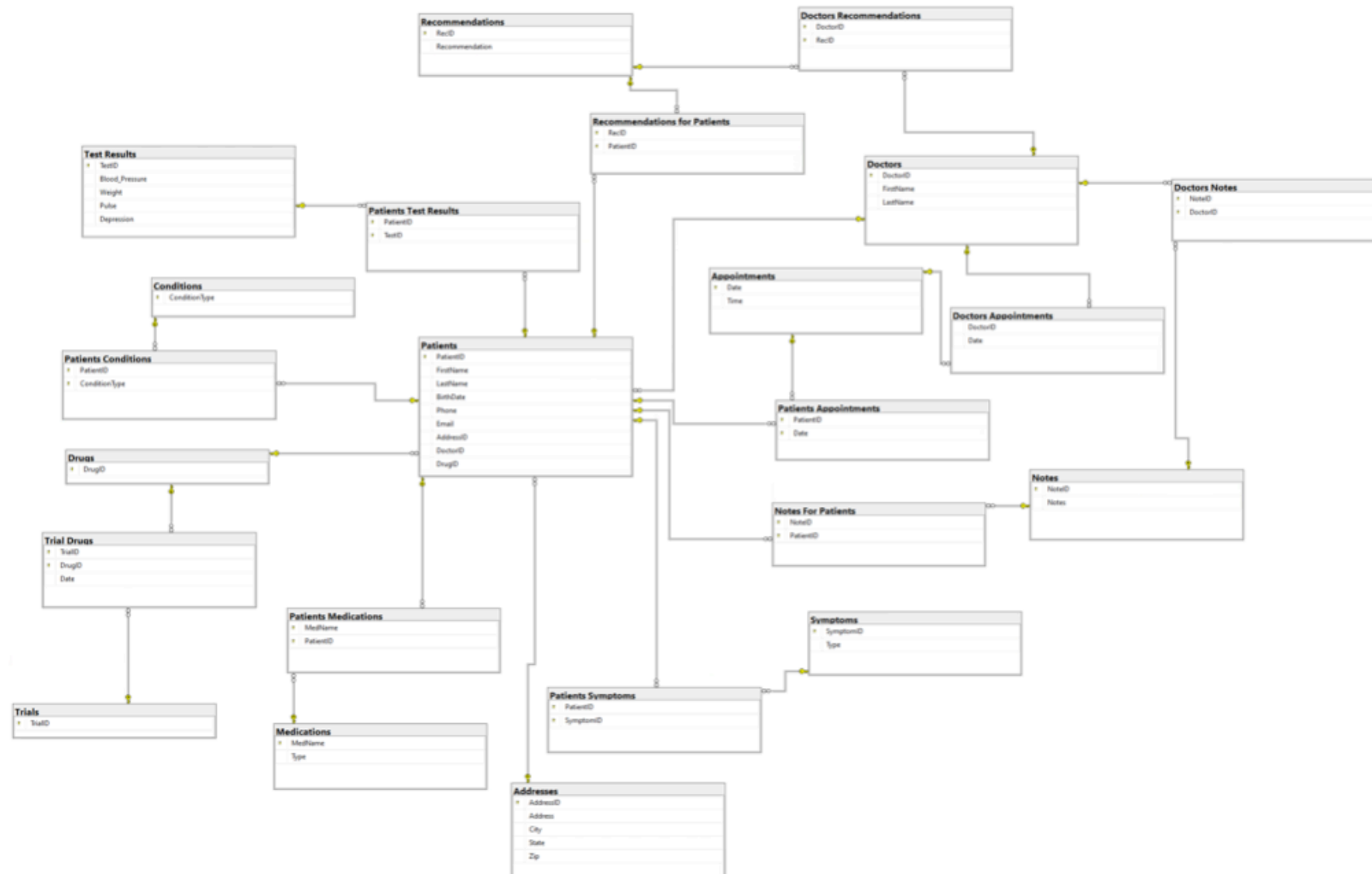
Enterprise Conceptual Entity Model (ECEM)

Overall, the "ECEM provides a data architectural framework for the organization's data designs and subsequent data stores, in support of data quality, scalability and integration" (Kendie, 2005)

The entities within the model represent the business lines and the data requirements for the organization and are "independent of technology and implementation concerns (Kendie, 2005)
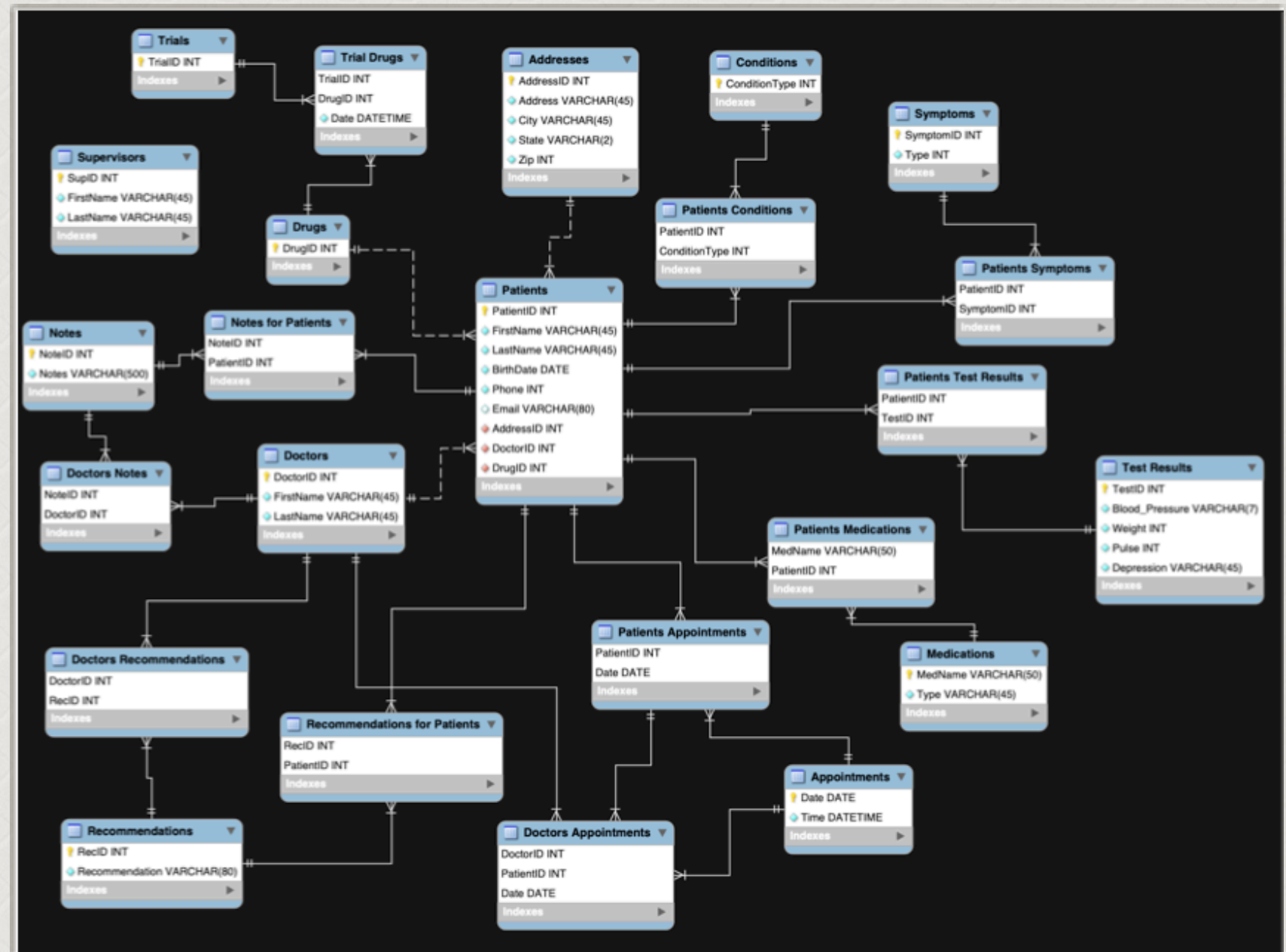
Database Operations and Rules

* *The database must collect and maintain sensitive data regarding patient history, current ailments and conditions, as well as trial test results*

* *Patients - observed by the doctors and are done so in periodic fashion, established by appointments, of which such interactions and observations are maintained in a log of notes and recommendations*

* *Doctors & Researchers - front-line observers and data collectors, maintain trustworthiness of the trial*

* *Medications - linked to specific trials, and records and results should be maintained for subsequent trials and review*

Database Security Management Plan & Legal and Ethical Considerations

- *Title II of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)*
- *The agreement established between an organization and its patients, clearly identifies and communicates the use and storage of the data be utilized and how it is being leveraged for a specific task*

- *Security Plan:*

  - *Ensure log-in credentials are strong in complexity, to deter unauthorized access*
  - *Enforce authentication and viewing constraints (stored procedures) for specified roles and ensure they are being routinely verified*
  - *Enforce encryptions to all data*
  - *Keep all relevant software and protocols updated and current*
  - *Maintain a secure storage of sensitive data (e.g., use strong passwords, install firewalls, intrusion prevention and intrusion detection systems) (UK Essays, 2017).*
  - *Established the Disaster Recovery Plan and disseminate the information to all internal stakeholders (Conger, 2014).*
  - *Backups (database, log files, system applications) should be conducted every 12 hours and stored off-site*
  - *Routine inventory of backup assets should be verified monthly*
  - *Document all database changes, updates, log reports, etc. for integrity and reproducibility purposes*

References:

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