

Clinical Trials Management System (CTMS) for neurological diseases

Our system's intent is to manage all the clinical trials for neurological diseases such as Alzheimer, Parkinson, multiple sclerosis,... Its aim is to store study information which consists in details about each clinical trial, patient data including patient personal information (id, name, blood group,...) as well as the patient's demographics (medical history,...), the treatments, investigational products (investigational drugs, devices,...) and their accountability, the doctors, the sponsors and the administrator.

The administrator will be able to create a new clinical trial and save it in the database system and he will also control the investments. The latter will be made by some sponsors. Once a patient has been diagnosed with that specific disease, he can apply for the clinical trial in the interest of receiving a new treatment which may be the cure for his disease. In order for the patient to be part of the clinical trial, the administrator has to approve the patient based on the preestablished requirements. The doctor will prepare a specific treatment for the clinical trial which will depend on the budget and amount of money invested by the sponsors. For that, he will need an engineer who will prepare the investigational drug. He will also be needed in order to create or help maintain/fix the machines if a technical problem occurs. In addition, the engineer will create investigational machines that will enable the progress of the investigation. Once the treatment has begun, the doctor will complete a lab results report every time the treatment has been implemented. The follow ups of the patient's disease and response to the treatment will be added. He will upload the reports containing the lab results and the patient's medical history to the database. Then, the sponsor will have access to them. The sponsors will be allowed to see and check the reports in order to decide if their investment is worthy or not, therefore, to decide if they want to keep investing. Once a patient is cured, the doctor will upload his condition. This will provide information about the trial's rate of success which will be only accessed by the administrator and the sponsor.

It's features:

- Actors: Doctor, Sponsor, Engineer, Administrator and Patient
- Administrator can:
 - Add a new clinical trial to which the patients can apply to
 - Add another administrator to the database
 - See all the patients that are saved in the database in order to manage their information
 - See all the administrators of the database
 - See the amount invested per trial in order to manage and control the investments. Check whether or not we have enough money to continue with the trial
 - See the trial applications of each patient and accept or deny them
 - Once accepted, he can assign the patient to a clinical trial
 - Delete a patient from a clinical trial
 - See all the patients of a specific trial

- See the rate of success of the trials
- Export data and load data from files

- Doctor:
 - Add another doctor to the database
 - See all the doctors that are in the database
 - Assign a doctor to a patient in order to treat him
 - Update a speciality of a doctor
 - Create a report (or follow-up) of the patient after receiving the treatment
 - Assign a report to a patient
 - See all the patients that are assigned to him
 - Show all the reports of a patient in order to keep track of any improvement or worsening in order to keep track of all the progress
 - Update cured state patient
 - Choose an investigational product in order to give a treatment
 - Export his data and load it from files

- Patient
 - Can apply to a clinical trial
 - See the state of his request
 - Once accepted and once the treatment has started, he can see all his reports
 - Export his data and load it from files

- Sponsor:
 - Add a new sponsor
 - See all the clinical trials in the database
 - Invest in a clinical trial (create an investment)
 - Update his investment
 - See and check the reports of a patient. That way, he can decide whether or not the investment is worth it.
 - See the success rate of the trials.
 - Export his data and load it from files

- Engineer:
 - Add a new engineer
 - See all the engineers in the database
 - Create an investigational product. He can create as many as he wants but just one at the time.
 - See all the investigational products that are stored in the database
 - See all the investigational products that are being used in one specific trial
 - Export his data and load it from files

- All of them have to register first so that can access the database and once registered, they can just login.
- They all have the option to change their password

We decided that we were going to have 5 actors which were going to be the administrator, doctor, patient, sponsor and engineer. Firstly, the patient is the key of a clinical trial, without them, the clinical trial would not be able to start. The administrator was chosen because we needed someone to manage all the data, medical and economic as well as the paperwork. We also needed an actor that was going to control the patients and their acceptance to the trials since they need to fulfill the requirements of the trial they apply to. Then, the doctor is essential in a clinical trial since he's the one who will assign the treatment and keep track of its progress. In addition, we decided to add the sponsor because a trial needs funds in order to keep researching. And finally, we needed some engineers. They are responsible for the creation of all the investigational products (drugs and machines) used in those trials.

The entities that are also present are trials applications, investigational products, trials and reports. The trials are the core of our database. They each need to have an amount of money invested to work. Without it, a trial cannot work. The investigational products are created by an engineer and they each have a type which can be drug or machine, a description and a cost. Finally, the reports are necessary for the clinical trial to remain in effect. It's needed for the sponsors to check the progress, for the doctors to see if there has been an improvement, a discovery,... All the entities have a common attribute which is an id so that they are identified and managed more efficiently.