HOG Clinical Trials Tracker

Project Step 2 Draft

Group 117

Team: Thomas Gathman, John Wong

## Feedback by Peer Reviewers:

The draft proposal for the HOG Clinical Trials Tracker received the following feedback.

* **Does the overview describe what problem is to be solved by a website with DB back end?**
  + Yes, the problem is clearly stated.
  + Yes, the team has a great idea with detailed solution that can be applied in the healthcare system; It is a very applicable solution to a big problem in the health care. Their approach can be solved using website with databases.
  + Yes, the Health Oncology Group (HOG) is a great idea and has a definite need in the healthcare space. The problem is laid out very well and described in detail.
  + Yes, it was made very clear that the Health Oncology Group is in need of a website with a DB back end after expanding their network and converting to an electronic system.
* **Does the overview list specific facts?**
  + Yes, there are multiple specific numbers used.
  + Yes, the tables have some facts; for example, clinical\_trail entity has clinical\_trail\_id and cancer\_type.
  + Yes, there is a lot of specific information in their overview.
  + Yes, the overview lists specific facts and statistics on the number of trials, participating hospitals and patients which allows us to infer the scale of the project.
* **Are at least four entities described and does each one represent a single idea to be stored as a list?**
  + Yes, there are five listed.
  + Yes, there are 5 entities.
  + Yes, five of them.
  + Yes, the entities are Clinical Trials, Patients, Employees, Patients and Hospitals and each one of them represents a single idea to be stored as a list.
* **Does the outline of entity details describe the purpose of each, list attribute datatypes and constraints** **and describe relationships between entities? Does the outline clearly indicate which entities (tables) will** **be implemented and which team member is primarily assigned to the associated page(s)?**
  + The entities have attributes and relationships specified and the purpose of each entity is clear. As for team members being assigned to pages, I'm not sure what 'pages' is referring to, but this part doesn't seem to be in the rubric so I don't think not including this should be a problem.
  + The purpose of each entity was described clearly with a separation section for each one; and each has its own attributes. The relations were well explained between entities.
  + Everything was described well, relationships included. I can clearly understand the need for each.
  + Yes, the entity outlines are very detailed with attribute names, datatypes and constraints. Additionally, all the relationships are clearly laid out. The outline does not indicate which tables will be implemented by which team member but I did not think this was a requirement of the assignment...
* **Are 1:M relationships correctly formulated? Is there at least one M:M relationship? Does the ERD** **present a logical view of the database?** 
  + Yes, the relationships are correctly formulated and there are 2 M:M relationships.
  + The team has multiple 1:M relationship; such as the relationship clinical\_trails and patients. There are 2 M:M relationship.
  + Yes everything seems to be correct and there are two M:M relationships.
  + Yes, the relationships are correctly formulated as far as I can tell and there are multiple M:M relationships. The ERD is easy to follow and aligns well with the entity outline section.
* **Is there consistency in a) naming between overview and entity/attributes b) entities plural, attributes** **singular c) use of capitalization for naming?** 
  + Yes, naming is very consistent.
  + I am amazed by how the team efforts to keep everything consistent and clearly explained. All the names of entities and attributes are written in same format.
  + Yes. Everything is named very well. This team went above and beyond. I think the idea is awesome and named very well. Great job!!!
  + Yes, there is consistency in the naming of entities and attributes, and the format is snake case.

## Actions Based on Feedback:

Because we did not include the team member primarily associated with each page, we added that to the proposal.

## Project Outline:

Health Oncology Group (HOG) is a National Cancer Institute (NCI) funded organization that conducts clinical trials of cancer treatments in adults. Increased participation from sites and patients in their clinical trials increased funding from the NCI and allowed HOG to expand their network. During the transition from paper to electronic records, a group of clinical trial recruiters have asked the software engineers to implement a database driven web application that centralizes the records of patients, personnel and sites associated with the clinical trials to keep up with the expansion.

Currently there are 25 clinical trials, with 100 participating hospitals/sites. On average each clinical trial plans to accrue a total of 300 patients over the length of approximately 2 years. Employees of multiple organizations can support the trials, and each clinical trial has at least one employee assigned to the trial; however, an employee may be assigned to work on multiple clinical trial projects. Some hospitals may also have multiple clinical trials occurring at their site; however, a patient at a hospital may only be enrolled in one clinical trial at a time.

HOG hopes to maintain a timeless database system that can track the accrual of patients for clinical trials and that can provide a current employee directory for staff to use over the life of the clinical trials. The electronic database will decrease the amount of paper records required and provide a central hub of information that will be immensely helpful for clinical trial recruiters.

## Database Outline:

As a result of the normalization process, a previously included attribute under clinical\_trials, *investigational\_treatment*, has been removed. Ultimately, the treatment is comprised of multiple drugs and multiple phases, which would have resulted in repeating groups. Instead of breaking this into additional entities, we decided to remove the attribute altogether, as we considered the needs of a recruiter, and ultimately, this would be extraneous information for them.

**clinical\_trials:**

Assigned Team Member: Thomas Gathman

Purpose:

An entity that stores information about the clinical trial including the trial id, type of cancer, investigational drug being used, trial description, and accrual goal (which is the maximum number of patients allowed on a trial).

Attributes:

* clinical\_trial\_id Primary Key: VARCHAR NN
* cancer\_type VARCHAR NN
* trial\_description VARCHAR NN
* maximum\_patients INT NN

Relationship:

* 1:M relationship between clinical\_trials and patients with *clinical\_trials\_clinical\_trial\_id* as a FK inside of patients; A clinical trial may have 0 or more patients.
* M:M relationship between clinical\_trials and hospitals; *clinical\_trials\_clinical\_trial\_id* and *hospitals\_hospital\_id* are FK in hospitals\_supporting\_clinical\_trials, an intersection table. Many clinical trials may be conducted by many hospitals.
* 1:M relationship between clinical\_trials and employees\_supporting\_clinical\_trials with *clinical\_trials\_clinical\_trial\_id* as a FK inside of *employees\_supporting\_clinical\_trials*; A clinical trial must have at least one employee in some supportive role.
* M:M Relationship between clinical\_trials and employees with *clinical\_trials\_clinical\_trial\_id* and *employees\_employee\_id* as FKs in employees\_supporting\_clinical\_trials, an intersection table turned entity due to the addition of an attribute; Many clinical trials must have at least one employee in a supportive role.

**employees\_supporting\_clinical\_trials**

Assigned Team Member: Thomas Gathman

Purpose:

An entity that stores information about the clinical trial and serves as the intersection table between clinical\_trials and employees due to the M:M relationship. This entity will have a composite attribute, *employee\_role*, that will allow an employee to have a specific role in one trial, while allowing for another role in another trial. This allows for the role to not be permanently tied to the employee entity.

Attributes:

* employees\_employee\_id Foreign Key: INT NN
* clinical\_trials\_clincal\_trial\_id Foreign Key: VARCHAR NN
* employee\_role VARCHAR

Relationship:

M:1 Relationship between employees\_supporting\_clincal\_trials and clinical\_trials; many employees will have at most one role in any given clinical trial.

M:1 Relationship between employees\_supporting\_clinical\_trials and employees; many employee roles may be assigned to any given employee.

**employees:**

Assigned Team Member: Thomas Gathman

Purpose:

An entity that stores information about the employee including the employee id, employee first and last name, employee’s position, employee’s contact information, and employee’s employer organization.

Attributes:

* employee\_id Primary Key: INT NN
* employee\_first\_name VARCHAR NN
* employee\_last\_name VARCHAR NN
* position VARCHAR NN
* email VARCHAR
* desk\_phone VARCHAR
* employer VARCHAR NN

Relationship:

* 1:M relationship between employees and employees\_supporting\_clinical\_trials with *employees\_employee\_id* as a FK in employees\_suporting\_clinical\_trials; An employee may have many roles, but only one role in a given clinical trial.
* M:M relationship between employees and clinical\_ trials with *clinical\_trials\_clinical\_trial\_id* and *employees\_employee\_id* as FKs in employees\_supporting\_clinical\_trials, an intersection table turned entity due to the addition of an attribute; Many employees may be working on 0 or more clinical trials.

**patients:**

Assigned Team Member: John Wong

Purpose:

An entity that stores information about the patient including their id, first and last name, address, and date of birth.

Attributes:

* patient\_id Primary Key: INT NN
* patient\_first\_name VARCHAR NN
* patient\_last\_name VARCHAR NN
* patient\_street VARCHAR NN
* patient\_city VARCHAR NN
* patient\_state VARCHAR NN
* patient\_zip VARCHAR NN
* patient\_sex CHAR NN
* dob DATE NN
* hospitals\_hospital\_id Foreign Key: INT NN
* clinical\_trials\_clinical\_trial\_ID VARCHAR NN

Relationship:

* M:1 relationship between patients and hospitals; Many patients must each go to exactly one hospital.
* M:1 relationship between patients and clinial\_trials; Many patients must each be on exactly one clinical trial.

**hospitals:**

Assigned Team Member: John Wong

Purpose:

An entity that stores information about the hospital or site including the hospital id, name, and address.

Attributes:

* hospital\_id Primary Key: INT NN, AI
* hospital\_name VARCHAR NN
* hospital\_street VARCHAR NN
* hospital\_city VARCHAR NN
* hospital\_state VARCHAR NN
* hospital\_zip VARCHAR NN

Relationship:

* 1:M relationship between hospitals and patients, with *hospitals\_hospital\_id* as a FK in patients; A hospital may have many patients.
* M:M relationship between hospitals and clinical trials, with *hospitals\_hospital\_id* and *clincical\_trials\_clinical\_trial\_id* as a FKs in hospitals\_supporting\_clinical\_trials, an intersection table; Many hospitals may have 0 or more clinical trials.

## Entity – Relationship Diagram:

Diagram

Description automatically generated

## Schema:

Graphical user interface, application

Description automatically generated

## Sample Data:

### clinical\_trials

|  |  |  |  |
| --- | --- | --- | --- |
| clinical\_trial\_id | cancer\_type | trial\_description | maximum\_patients |
| HG1141 | Breast | This randomized phase II trial studies how well abbreviated breast magnetic resonance imaging (MRI) and digital tomosynthesis mammography work in detecting cancer in women with dense breasts. | 1500 |
| HG8143 | Kidney | This phase III trial compares nephrectomy (surgery to remove a kidney or part of a kidney) with nivolumab to the usual approach of nephrectomy followed by standard post-operative follow-up and monitoring. | 750 |
| HGG173 | Myeloma | This phase III trial studies how well lenalidomide and dexamethasone works with or without daratumumab in treating patients with high-risk smoldering myeloma. | 300 |

### hospitals\_supporting\_clinical\_trials

|  |  |
| --- | --- |
| clinical\_trials\_clinical\_trial\_id | hospitals\_hospital\_id |
| HG1141 | 1 |
| HG1141 | 3 |
| HG8143 | 2 |
| HGG173 | 3 |

### hospitals

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| hospital\_id | hospital\_name | hospital\_street | hospital\_city | hospital\_state | hospital\_zip |
| 1 | Baylor University Medical Center | 3500 Gaston Ave | Dallas | TX | 75246 |
| 2 | Case Western Reserve University | 9501 Euclid Ave | Cleveland | OH | 44106 |
| 3 | Geisinger Medical Center | 100 N Academy Ave | Danville | PA | 17821 |

### patients

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| patient\_id | patient\_first\_name | patient\_last\_name | patient\_street | patient\_city | patient\_state | patient\_zip | patient\_sex | dob | hospitals\_hospital\_id | clinical\_trials\_clinical\_trial\_id |
| 10001 | Gaviin | Jep | 9020 Garland Rd | Dallas | TX | 75218 | M | 11/1/2000 | 1 | HG1141 |
| 13001 | Herbie | Williams | 2136 Murray Hill Rd | Cleveland | OH | 44106 | M | 9/21/1995 | 2 | HG8143 |
| 38001 | Terry | Noel | 502 Church St | Danville | PA | 17821 | F | 2/28/2000 | 3 | HGG173 |
| 38002 | Paden | Heidi | 331 W Mahoning St | Danville | PA | 17821 | F | 8/27/1984 | 3 | HG1141 |

### employees\_supporting\_clinical\_trials

|  |  |  |
| --- | --- | --- |
| employees\_employee\_id | clinical\_trials\_clinical\_trial\_id | employee\_role |
| 1 | HG1141 | Recruiter |
| 2 | HG8143 | Project Coordinator |
| 3 | HGG173 | Data Manager |
| 4 | HG1141 | Study Chair |
| 5 | HG8143 | Committee Chair |
| 6 | HGG173 | Study Co-Chair |

### employees

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| employee\_id | employee\_first\_name | employee\_last\_name | position | email | desk\_phone | employer |
| 1 | Regina | Dutch | Recruiter | dregina@hog.com | 402-250-8329 | Health Oncology Group |
| 2 | Calvin | Jonas | Project Coordinator | cjonas@hog.com | 714-338-2340 | Health Oncology Group |
| 3 | Haylie | Sandra | Data Manager | hsandra@hog.com | 832-209-6628 | Health Oncology Group |
| 4 | Steve | Glenna | M.D. | sglenna@case.edu | 775-981-5220 | Case Western Reserve University |
| 5 | Deitra | Gracie | M.D. | dgracie@baylor.edu | 561-552-5564 | Baylor University Medical Center |
| 6 | Alex | King | M.D. | aking@geisinger.edu | 914-774-0513 | Geisinger Medical Center |