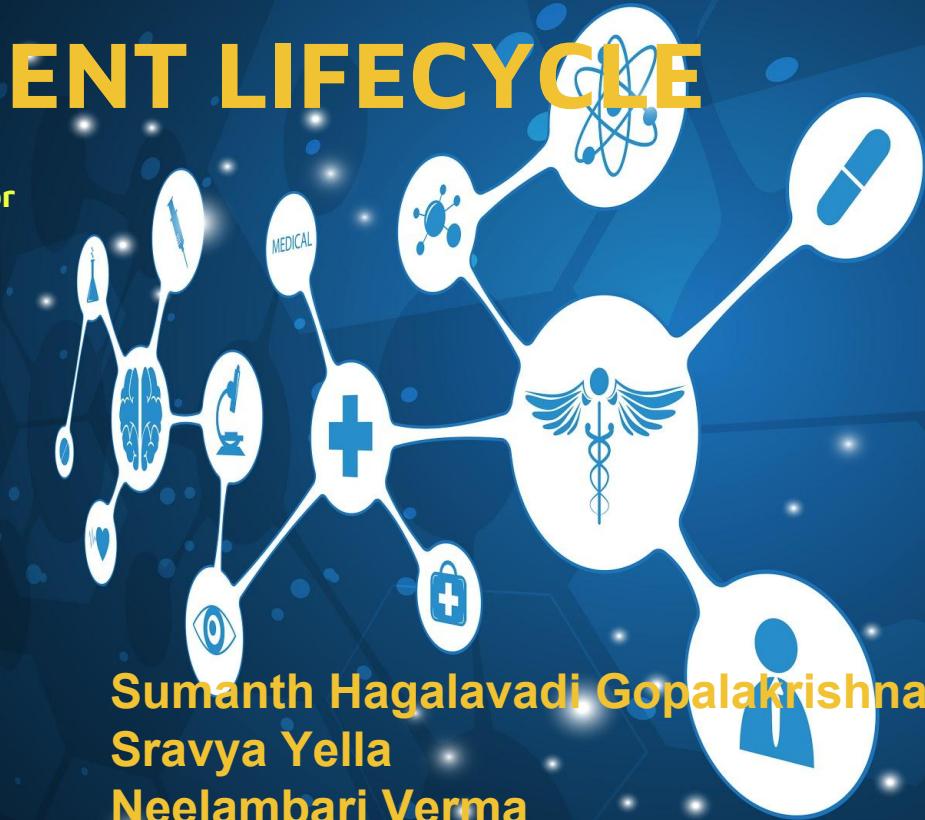


DRUG DEVELOPMENT LIFECYCLE

Exploring the adverse effects of drugs eco-system for patient centered care.



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Description

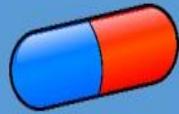
The project is a Drug Development life cycle ecosystem that work on the creation of drugs and adverse effects of drugs on the patient's. Also action taken and penalties that have been charged by the administration i.e. FDA (Food and Drug Administration) on drug companies to solve issues. The drug is approved/denied based on the adverse effects on the individual cases in history.



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Life Cycle of a Drug

Discovery



Preclinical



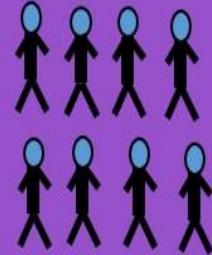
Clinical
trials



Approval



Post-
approval



Problem Statement

- 1. Taking the drug based on the disease and adverse effect caused by the drug.**
- 2. Adverse effects of a drug on different kinds of patient's.**
- 3. Approving the request from FDA and sending the score of the Lab report via Email.**
- 4. Drug creation and side effects on people.**
- 5. Safety Procedure implementation of drugs which has been manufactured.**



Solution to Denial of drugs

Insurance organisation involves when a drug is denied by FDA and pays the penalty for the user who are part of clinical trials. Also, the drug is banned further in the market.

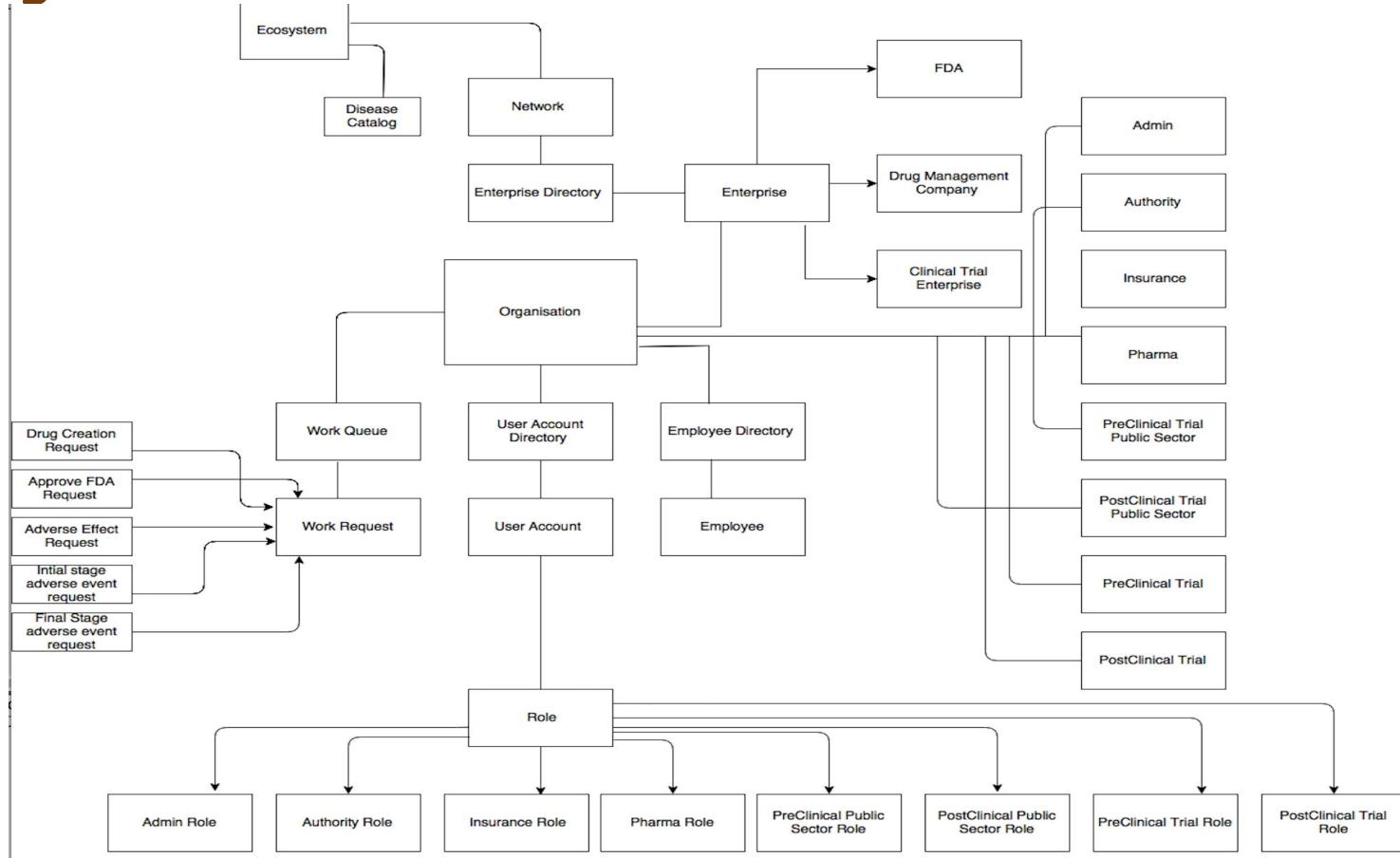


Special Features



1. Adding IoT feature of email to send request to Authority from PreClinical Trial and Post Clinical Trial report via Email.
2. Implementing Naranjo Algorithm to create the Lab report which is defined by FDA.
3. Adding Multithreading feature when there is more processing in the application.
4. Interpretation of Adverse event scores are analysed and based on the analysis, reports are created which is sent via emails.
5. Showing Interpretation scores on progress bar, pie charts, and loading scale.

Object Model



Key roles

- 1. Admin Role**
- 2. Authority Role**
- 3. Insurance Role**
- 4. Pharma Role**
- 5. PreClinical trial Role**
- 6. PostClinical trial Role**
- 7. PreClinical Public Sector Role**
- 8. PostClinical Public Sector Role**
- 9. System Admin Role**



Use Cases

- ❖ Involving Patient for test cases.
- ❖ Sending request from Pharma to FDA.
- ❖ Approving request from FDA and sending request to Pre- Clinical and Post- Clinical Trial Organization.
- ❖ Clinical trial will process the request and do calculation according to **Naranjo algorithm**.
- ❖ This score which has been calculated will be sent via Email along with report and request to FDA.
- ❖ FDA can view the completed request score report.
- ❖ Based on the interpretation score, FDA decides the drug status.
- ❖ Insurance organization will take money from pharma company and distributes to people who has undergone clinical trials.



Screenshots of the Project

Login page:



Explorers

After logging in

User Name

Password

Login 

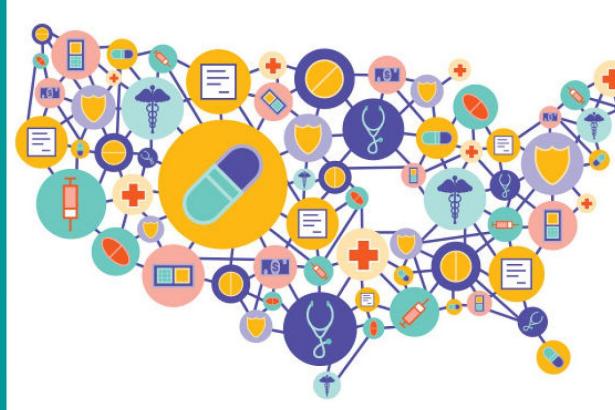
Logout

System
 ▶ Networks

System Admin Work Area

Selected Node: <view_selected_node>

- Manage Network
- Manage Enterprise
- Manage Enterprise Admin
- Manage Disease Catalog



Drug Management Organisation

The image shows a screenshot of a software application window titled "Drug Management Organisation". On the left side, there is a sidebar with a user profile icon, a "User Name" field containing "dmg", a "Password" field with three asterisks, a "Login" button with a checkmark icon, and a "Logout" button.

The main content area is titled "Manage Employee". It contains a form for managing employees. The "Organization" dropdown is set to "Pharma Organization". The "Name" field contains "pharma". There are two buttons on the right: "Update" and "Delete Employee".

Below this, there is another set of fields for managing employees. The "Organization" dropdown is again set to "Pharma Organization". The "Name" field is empty. To its right is a "Disease Catalog" dropdown set to "Cancer". Below these are fields for "Vaccine Name:" and "Insurance Money Reserved", both of which are empty. At the bottom of this section are buttons for "<< Back" and "Create Employee".

Pharma Request

Pharma Work Area

User Name: ph
Password: ph

Login 

Logout

Enterprise : dmg
Organization: Pharma Organizati...

Employee Name: ph

Disease: Cancer

Vaccine: v2

Insurance Money: 345454.0

Send request about drug manufacture

Message	Receiver	Status	Result	Request Date	Completed Date

Pharma Request Work Area

User Name: ph
Password: ph

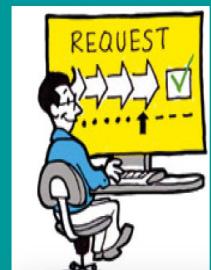
Login 

Logout

Message: Need Help

<<Back

Request for Approval of Drug



Message

i Request sent successfully

OK

Pre Clinical Public Sector Work Area

The screenshot shows a Java Swing application window titled "Pre-Clinical Public Sector Work Area". The window has a teal header bar and a white content area. On the left side, there is a sidebar with a user icon, "User Name" field containing "p2", "Password" field containing "##", a "Login" button with a green checkmark icon, and a "Logout" button.

The main content area displays a table of patient data:

Name	Age	Disease
Jenna	64	Arthritis
Wyoming	29	Arthritis
Jessica	40	Arthritis
John	59	Cancer
Stuart	63	Cancer
Jennifer	65	Cancer
Sasha	19	Asthma
Yasmeen	35	Asthma
yashira	60	Asthma

At the bottom of the content area, there are buttons for "Search by Name :" (with a yellow border), "Add", "Update", and "Delete".

Pre Clinical Trial Organization

The screenshot shows a teal-themed application window. On the left, there's a sidebar with a user icon, fields for 'User Name' (p1) and 'Password', and buttons for 'Login' (with a checkmark) and 'Logout'. The main area has sections for 'Enterprise' (ct), 'Organization' (Pre Clinical Trial Organization), and 'Employee Name' (pre). It displays a table of messages:

User who raised req...	Message	Sender	Receiver	Status
ao	Need Help	ao	p1	Approved drug for initial Test

At the bottom are 'Process Request' and 'Complete Request' buttons.

The screenshot shows a teal-themed application window titled 'Pre Clinical Trial Process Panel'. It includes a sidebar with a user icon, fields for 'User Name' (p1) and 'Password', and buttons for 'Login' (with a checkmark) and 'Logout'. The main panel has a title 'Pre Clinical Trial Process Panel' and fields for 'Select Person' (set to John) and 'Disease' (Cancer).

The process consists of several questions:

1. Are there previous conclusive reports on this reaction?
Radio buttons: Yes (unchecked), No (checked)
2. Did the adverse event appear after the suspected drug was administered?
Radio buttons: Yes (unchecked), No (checked)
3. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?
Radio buttons: Yes (unchecked), No (checked)
4. Did the adverse reaction reappear when the drug was readministered?
Radio buttons: Yes (unchecked), No (checked)
5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?
Radio buttons: Yes (unchecked), No (checked)
6. Anemia Increased Percentage of Increase/Decrease 23
7. unusual mole Increased Percentage of Increase/Decrease 56
8. Did the reaction reappear when a placebo was given?
Radio buttons: Yes (unchecked), No (checked)
9. Was the drug detected in the blood (or other fluids) in concentrations known to be toxic?
Radio buttons: Yes (unchecked), No (checked)
10. Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?
Radio buttons: Yes (unchecked), No (checked)

A modal dialog box is open, displaying a message: 'Request completed' with an 'OK' button.

Email Request

Enter Email to send request: neelambari.verma@gmail.com





Final Score Using Naranjo Algorithm

The screenshot shows a web-based application for calculating the Naranjo Adverse Effect Score. The interface includes a header with a user icon, 'User Name' (ao), 'Password' (xx), 'Login' button (with checked status), and 'Logout' button. A dropdown menu 'Select Person' shows 'John'. A horizontal scale at the top ranges from -15 to 15, with a marker at 7.

The main area displays 13 questions with numerical answers:

- 1. Are there previous conclusive reports on this reaction? 0
- 2. Did the adverse event appear after the suspected drug was administered? -1
- 3. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered? 0
- 4. Did the adverse reaction reappear when the drug was readministered? 0
- 5. Are there alternative causes (other than the drug) that could on their own have caused the reaction? 0
- 6. Side Effect Anemia: Increased 1
- 7. Side Effect unusual mole: Increased 3
- 8. Did the reaction reappear when a placebo was given? 1
- 9. Was the drug detected in the blood (or other fluids) in concentrations known to be toxic? 0
- 10. Was the reaction more severe when the dose was increased, or less severe when the dose was decreased? 0
- 11. 0
- 12. 0
- 13. Side Effect cough: Increased 2

Below the questions, a 'Total Score' is displayed as 7.0. At the bottom, there are buttons for '[<< Back](#)', [Approve Drug for Post Clinical Trial](#), and [Deny Drug](#).

A modal dialog box is overlaid on the page, titled 'Warning', containing the question 'Would you like to Approve and pass request to Post Clinical trial?' with 'No' and 'Yes' buttons. This dialog is circled in red.

Drug is approved or banned based on the Adverse effect Score

Post Clinical Trial Process Panel

The screenshot shows a user interface for a clinical trial process panel. On the left, there is a sidebar with a user icon, 'User Name' field (p.3), 'Password' field (*****), 'Login' button, and 'Logout' button. The main area is titled 'Post Clinical Trial Process Panel' and contains 13 questions. Questions 1 through 6 are grouped together, and questions 7 through 13 are grouped together. Each question has a radio button for 'Yes' or 'No'. Questions 6, 7, 8, 10, 11, 12, and 13 have dropdown menus below them labeled 'Increased', 'Decreased', and 'Normal'. A 'Proceed For Calculation' button is located at the bottom right.

User Interface Elements:

- Left Sidebar:** Includes a user icon, 'User Name' field (p.3), 'Password' field (*****), 'Login' button, and 'Logout' button.
- Main Title:** 'Post Clinical Trial Process Panel'
- Questions and Responses:**
 - 1. Are there previous conclusive reports on this reaction?
No (radio selected)
 - 2. Did the adverse event appear after the suspected drug was administered?
No (radio selected)
 - 3. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?
No (radio selected)
 - 4. Did the adverse reaction reappear when the drug was readministered?
No (radio selected)
 - 5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?
No (radio selected)
 - 6. Tiredness (Common Side Effects greater than 50%)
Increased (dropdown selected)
 - 7. unusual mole (Common Side Effects greater than 25%)
Increased (dropdown selected)
 - 8. Did the reaction reappear when a placebo was given?
No (radio selected)
 - 9. Was the drug detected in the blood (or other fluids) in concentrations known to be toxic?
No (radio selected)
 - 10. Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?
No (radio selected)
 - 11. Did the patient have a similar reaction to the same or similar drugs in any previous exposure?
No (radio selected)
 - 12. Was the adverse event confirmed by any objective evidence?
No (radio selected)
 - 13. cough (Common Side Effects less than 25%)
Increased (dropdown selected)
- Buttons:** 'Proceed For Calculation' button.

Post Clinical Trial Calculation Panel

Calculation of adverse effects of drug is performed based on multi-threading feature.

The screenshot displays two identical instances of the "Post Clinical Trial Calculation Panel" application side-by-side. Both instances have a teal header bar with the title "Post Clinical Trial Calculation Panel". On the left, there is a sidebar with a user icon, fields for "User Name" (p3) and "Password" (p3), and buttons for "Login" (with a checked checkbox) and "Logout". The main area contains a "Start Computation" button in a pink box and a list of calculation status messages. Below this is a table showing person names, scores, and drug valid status. At the bottom, there is a "Final Interpretation Score" input field and a "Back" button.

Left Instance Status Messages:

- Jane Calculation Started
- Jane Calculation Completed
- will Calculation Started
- will Calculation Completed
- jelly Calculation Started

Table Data (Left Instance):

Person Name	Score	Drug Valid Status
Jane	11	Definite Adverse Event
will	10	Definite Adverse Event

Right Instance Status Messages:

- Jane Calculation Started
- Jane Calculation Completed
- will Calculation Started
- will Calculation Completed
- jelly Calculation Started
- jelly Calculation Completed
- joy Calculation Started
- joy Calculation Completed
- shaley Calculation Started
- shaley Calculation Completed
- shazzy Calculation Started
- shazzy Calculation Completed
- sartz Calculation Started
- sartz Calculation Completed
- collen Calculation Started
- collen Calculation Completed
- edward Calculation Started
- edward Calculation Completed
- Jacob Calculation Started

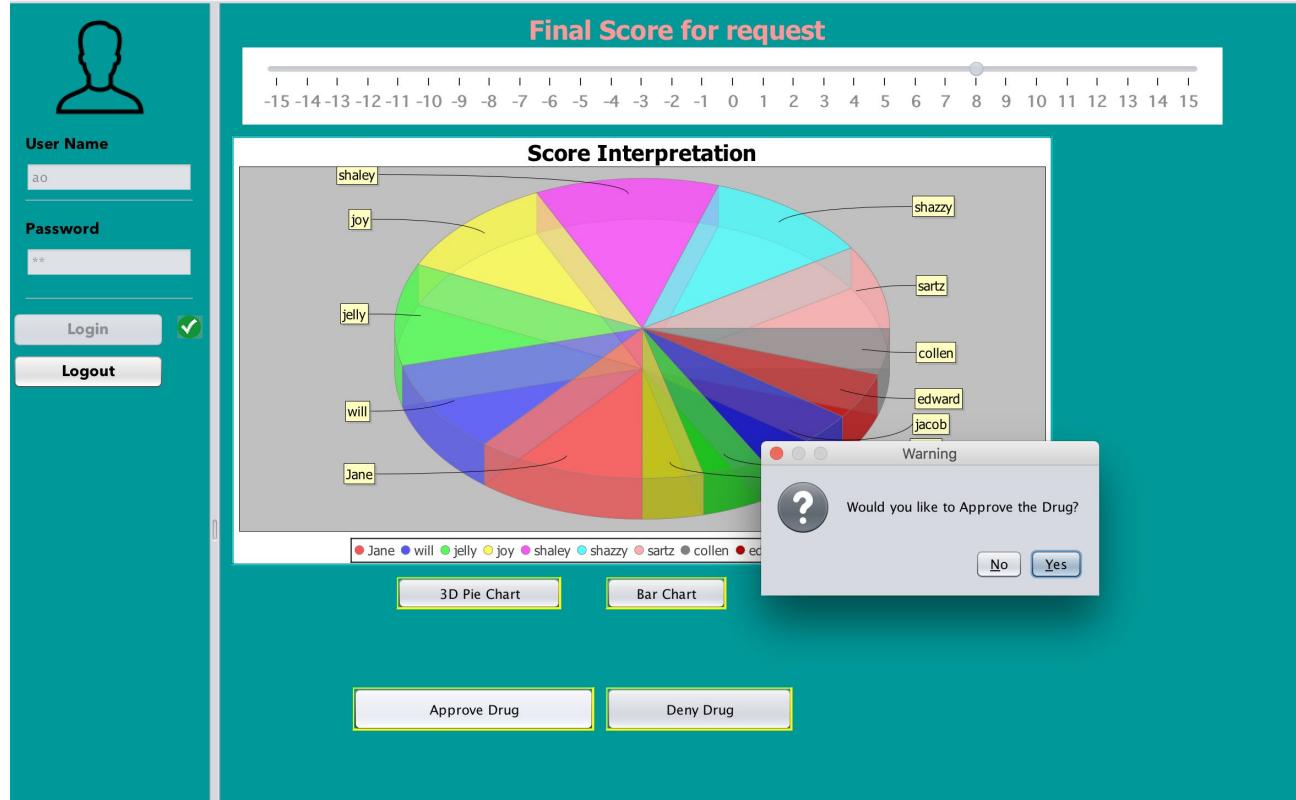
Table Data (Right Instance):

Person Name	Score	Drug Valid Status
Jane	11	Definite Adverse Event
will	10	Definite Adverse Event
jelly	11	Definite Adverse Event
joy	11	Definite Adverse Event
shaley	12	Definite Adverse Event
shazzy	11	Definite Adverse Event
sartz	9	Definite Adverse Event
collen	5	Probable Adverse Event
edward	5	Probable Adverse Event
Jacob	7	Probable Adverse Event
bella	4	Possible Adverse Event
bin	4	Possible Adverse Event

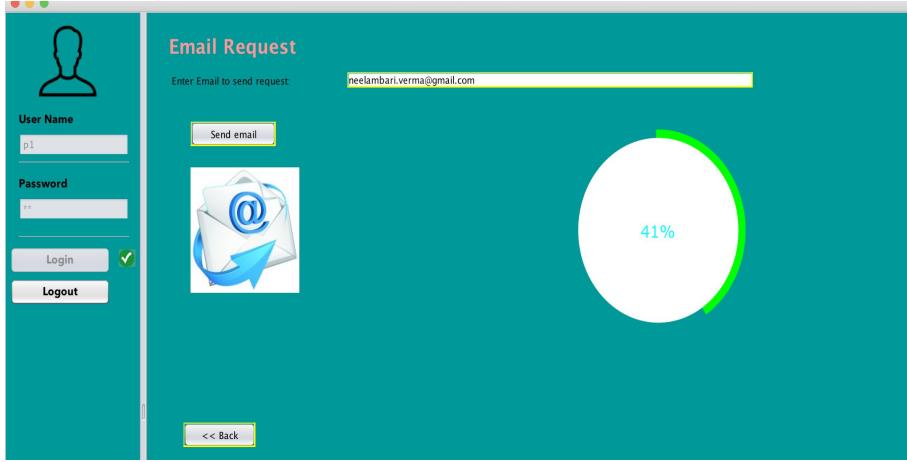
Message Box (Right Instance):

Message
Computation Completed
OK

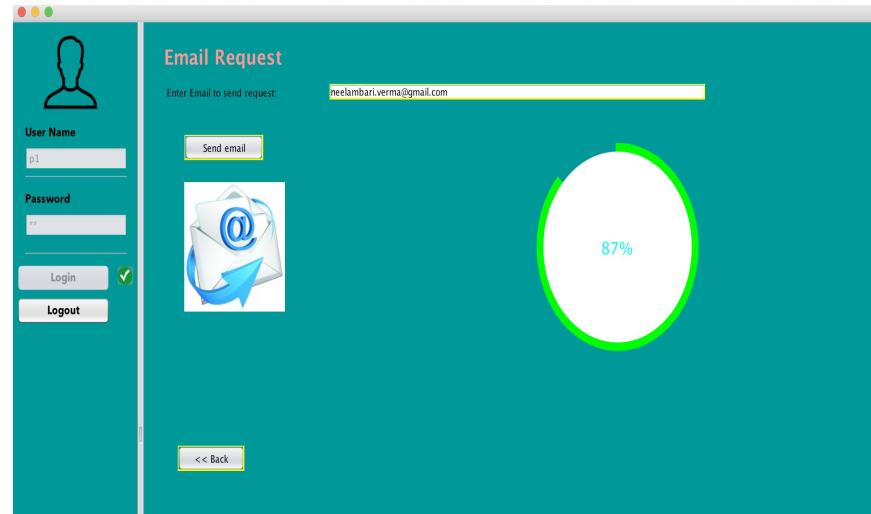
Final Score in Pie and Bar Chart



Email Request



Email Request with
loading feature based on
threads.



Penalty for banned drugs



User Name
ao

Password

Login

Logout

Final Score for request

Score: 9.0

Select Person: John

1. Are there previous conclusive reports on this reaction? 0

2. Did the adverse event appear after the suspected drug was administered? -1

3. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered? 0

4. Did the adverse reaction reappear when the drug was readministered? -1

5. Are there alternative causes (other than the drug) that could on their own have caused the reaction? 2

6. Side Effect Anemia: Increased 2

7. Side Effect unusual mole: Increased 3

8. Did the reaction reappear when a placebo was given? 1

9. Was the drug detected in the blood (or other fluids) in concentrations known to be toxic? 0

10. Was the reaction more severe when the dose was increased, or less severe when the dose was decreased? 0

11. Did the reaction occur at a similar time as a similar drug? 0

12. Did the reaction occur at a similar place as a similar drug? 0

13. Side Effect cough: Increased 3

Total Score: 9.0

<< Back Approve Drug for Post Clinical Trial Deny Drug

Warning
Would you like to Deny the drug?
Deny Drug?

Insurance Organization Work Area



User Name
io

Password
**

Login

Logout

Insurance Work Area

EnterPrise : fda

Organization: Insurance Organization

Employee Name: io

User who raised request	Message	Sender	Receiver	Status
ao	Fracture	ao	io	Pre Clinical Trial Denied



Distribute money

Money Distributed to the user



User Name
io

Password
**

Login

Logout

Distribution of Money for Pre Clinical Trial

Available Money 45464.0 Money To be distributed 4000 Distribute Money

Person	Age	Interpretation Value	Insurance Money Given

<< Back



Naranjo Algorithm

- ❖ **Pre Clinical Trial**
- ❖ Naranjo Algorithm will process based on the question answered by Pre Clinical Trial Organization.
- ❖ Along with question, major side effects will be considered and based the percentage of increase or decrease of these side effects, scores will be predicted.
- ❖ Final score will be the average of the interpretation scores on all person in the clinical trial
- ❖ **Post Clinical Trial**
- ❖ Large number of people will be considered in the Post clinical trial organization and same Naranjo Algorithm questions will be considered for calculation of interpretation scores
- ❖ Along with the questions, Percentage of common side effects and age of the person will be considered for calculation of side effects.
- ❖ Naranjo scores of 9 or 10 indicate that an event was "definitely" an Adverse Drug Reaction; scores of 5-8 rate the likelihood as "probable" Adverse Drug Reaction; scores of 1-4 are "possible" Adverse Drug Reaction; and scores of less than 1 are "doubtful. Adverse Drug Reaction".

Joint Pain increased



Continued...

For Pre Clinical Trial, Calculation of score based on side effects are as follows:

If the side effect is increased , then accordingly 1,2,3,4 values will be assigned based on percentage and if side effects are reduced, scores of 1,2,3,4 will be assigned in negative values.

For PostClinical Trial, Calculation of score based on Common side effects are as follows:

If the common side effect is increased based on percentage, values ranging from 3 to 12 will be added to the final score and if its decreased, scores will be assigned in negative values.

Pharma-FDA-PreClinical-Insurance Social Network

- ❖ Pharma sends requests for vaccines to FDA for initial approval.
- ❖ Pre-clinical trial and Post clinical trial have their own Lab reports which is sent for approval.
- ❖ Approval/Denial based on the score of the adverse effects for that particular drug.
- ❖ Insurance organisation will provide the penalty if it exceeds the threshold.

