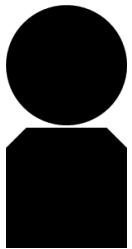


Consumer Persona



Patient

Attributes

- Age Between 25-50
- Computer Literate
- Limited Medical Knowledge

Goals

- Identify Drug interactions and minimize risk adverse reactions

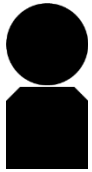
Concerns

- Consumable Information
- Easy to search for
- Time spent searching for information
- Accuracy

Product use and activity

- Intermittent use
- Searches for drug interactions

Pharmaceutical Persona



**Pharmaceutical
Manufacturer
Employee**

Attributes

- Age Between 30-60
- Expert computer skills
- Bioinformatics specialist
- Doctorate degree

Goals

- Pharmaceutical research
- Finds Correlations and patterns in the data

Concerns

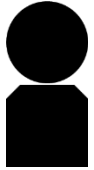
- Comprehensive information
- Accuracy
- Efficiency of Application
- Rapid results

Product use and activity

- Consistent use
- Search for patterns and correlations across datasets



Regulator Persona



Regulator

Attributes

- Age Between 45-60
- Expert computer skills
- In depth knowledge policies and procedures
- Masters degree or greater

Goals

- Public Safety
- Ensure pharmaceutical manufacturers and researchers are compliant with policy and procedures

Concerns

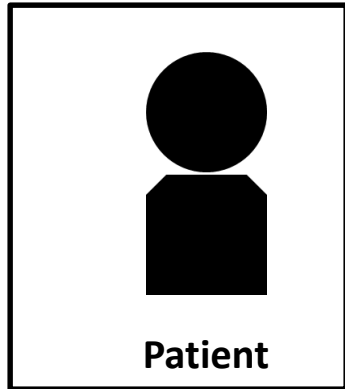
- Comprehensive information
- Accuracy
- Efficiency of Application
- Rapid results

Product use and activity

- Consistent use
- Verify products are compliant with regulatory policy and procedures



User Stories and Use Case Justification



User Stories

There are more opportunities today than ever before to learn about your health and to take better care of yourself. It is also more important than ever to know about the medicines and food you take. If you take several different medicines, see more than one doctor, or have certain health conditions, you and your doctors need to be aware of all the medicines you take. Doing so will help you to avoid potential problems such as drug interactions and food interactions.

Justification of the Use Case

One example is that, Michele Jackson was taking drugs for skin disease, depression, sleeping fovea, etc. Hence he used anesthesia drug used in the surgery to avoid sleeping fovea.

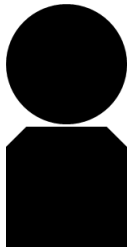
IF openFDA implements Drug→Drug and Drug→Food use case then we could save missions of life's, like Michele Jackson.

This is a great value add to the FDA agency and a great value proposition/ ROI for openFDA.





Use Case 1 – Drug → Drug Adverse Reactions



Patient



Use-Case-1 - Drug-drug, drug-adverse events interaction checks

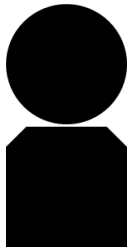
- **Interventions**. When a patient enters the list of medications (drug) he/she currently is currently prescribed in the openFDA website and then using the openFDA data set, interventions must automatically and electronically indicate to a user drug-drug and drug-reaction/warning Adverse Events based on a patient's medication list. Drugs include Medications prescribed by the Medical Practitioner and over the counter medications.
- Enable the **severity level** (Very Serious, Serious, and Less Serious) of interventions provided for drug-drug interaction checks to be adjusted.
- Adjustments of drugs by removing or adding new drug or increasing/ decreasing the drug dose, till LESS SEVIREITY are indicated to the patient.

Example

Drug-condition interactions may occur when an existing medical condition makes certain drugs potentially harmful. For example, if you have high blood pressure you could experience an unwanted reaction if you take a nasal decongestant.



Use Case 2 – Drug → Food Adverse Reactions



Patient



Use-Case-1 - Drug-drug, drug-adverse events interaction checks

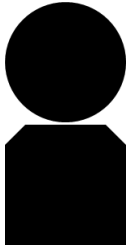
- **Interventions**. When a patient enters the list of medications (drug) he/she currently is currently prescribed in the openFDA website and then using the openFDA data set, interventions must automatically and electronically indicate to a user drug-food and food-reaction/warning Adverse Events based on a patient's medication list. Drugs include Medications prescribed by the Medical Practitioner and over the counter medications.
- Enable the **severity level** (Very Serious, Serious, and Less Serious) of interventions provided for drug-food interaction checks to be adjusted.
- Adjustments of drugs by removing or adding new drug or increasing/ decreasing the drug dose, till LESS SEVIREITY are indicated to the patient.

Example

Drug-food/beverage interactions result from drugs reacting with foods or beverages. For example, mixing grape fruit juice with some drugs like Satin may cause adverse events or slow your reactions for the drug.



Use Case 3 – Generic User Experience



Patient
FDA Regulator
Pharm Manufacturer



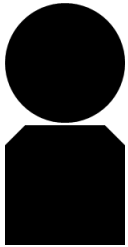
Use-Case-1 - Drug-Food, Warnings, ask doctor, pregnancy guidelines interaction checks

- **Interventions**. When a patient/FDA regulator/ Pharma Manufacturer enters the list of medications (drug) he/she currently is currently prescribed in the openFDA website and then using the openFDA data set, interventions must automatically and electronically indicate to a user drug, food, ask doctor, pregnancy guidelines and adverse reaction/warning Adverse Events based on medication list. Drugs include Medications prescribed by the Medical Practitioner and over the counter medications.

Example

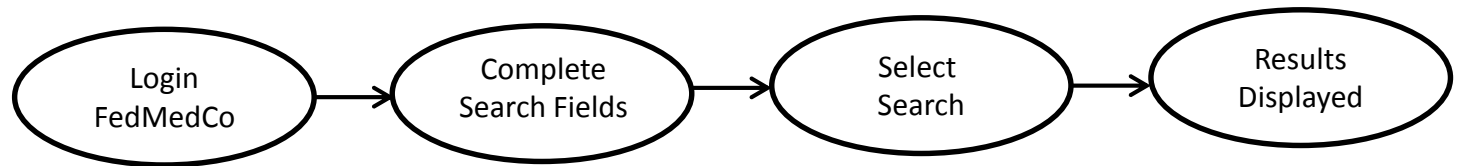
This is a deep dive generic use case where the FDA stakeholders can obtain more information like drug, food, ask doctor, pregnancy guidelines and adverse reaction/warning Adverse Events interactions more information's.

Scenario Example



Patient

Common reported drug reactions

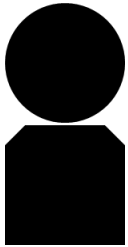


<input generic drug name>

Display top three results in order of likelihood of occurrence.

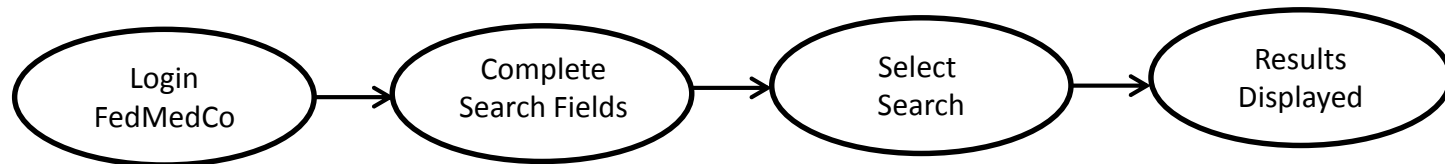
Display links to remaining results for Serious, Moderate, and Mild reactions

Scenario Example



Patient

Interesting Facts about you medicine

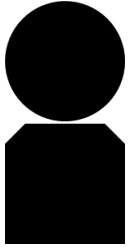


<input generic drug name>

Display:

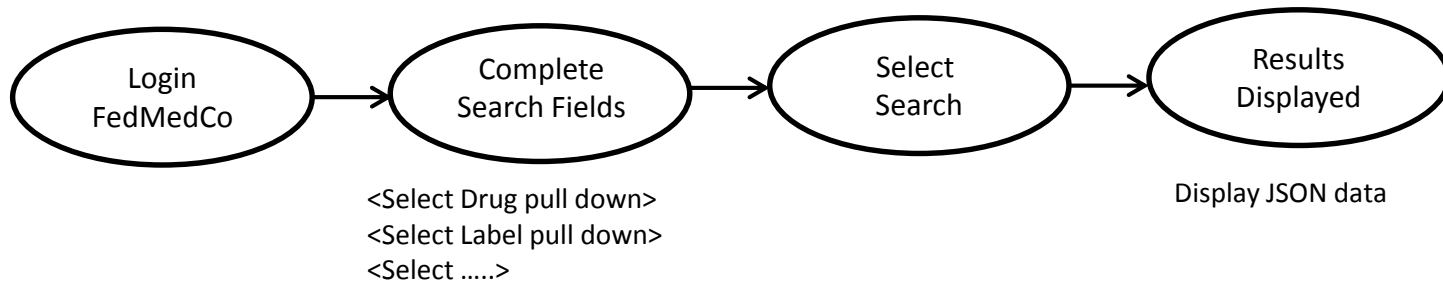
- Purpose
- Stop using If
- Storage and Handling
- What to ask Doctor
- Warnings

Scenario Example



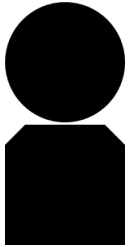
Pharmaceutical
Manufacturer
Representative

Open FDA Search



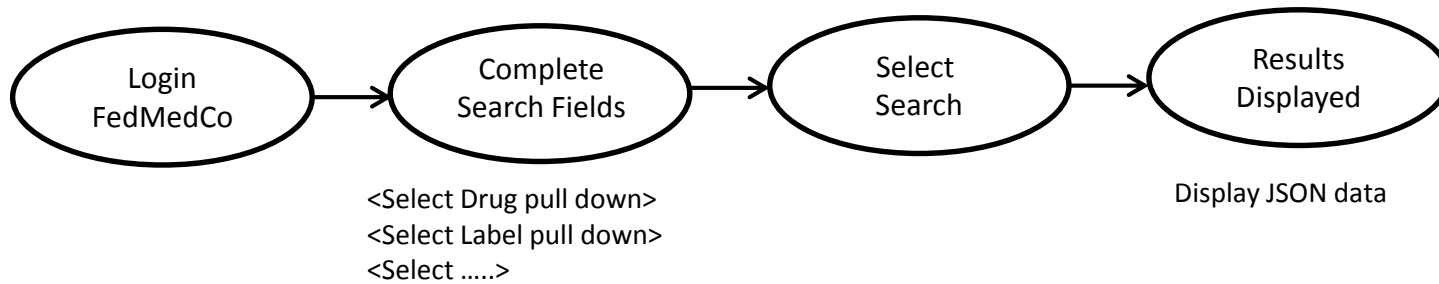
Display JSON data

Scenario Example



Regulatory
Professional

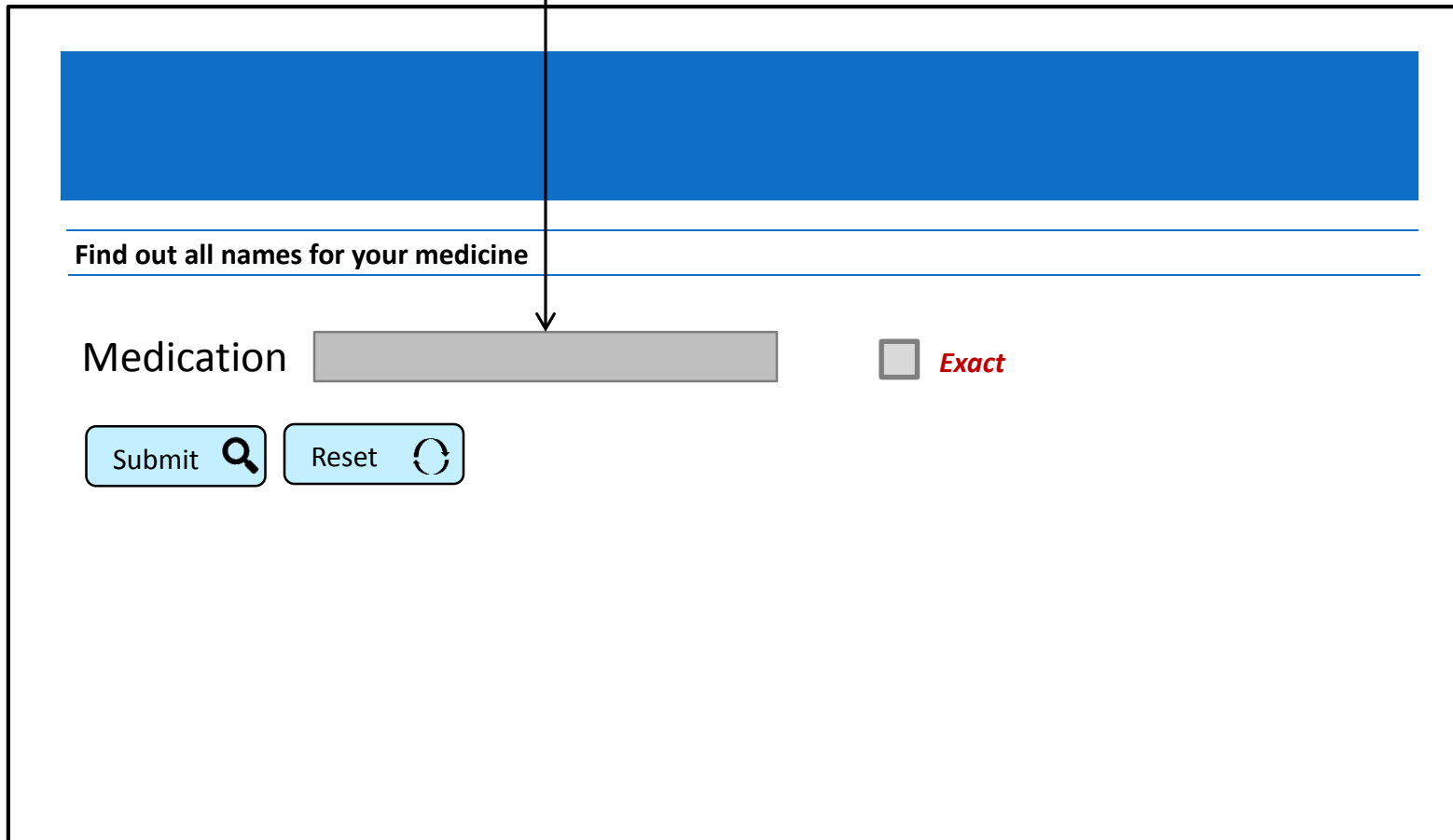
Open FDA Search



Find out names for your medication



Behavior = should start narrowing list as I put characters in the field

A screenshot of a web application for finding medication names. At the top, there is a large blue rectangular area. Below it, the text "Find out all names for your medicine" is displayed. A vertical arrow points from the blue area down to a search input field. The input field is preceded by the label "Medication". To the right of the input field is a checkbox labeled "Exact". Below the input field are two buttons: "Submit" with a magnifying glass icon, and "Reset" with a circular arrow icon.

Find out all names for your medicine

Medication

☐ *Exact*

Name for Medicines Result Screen



Behavior = should start narrowing list as I put characters in the field

All known names for Drug XXXXXXXX

Generic Name:

XXXXXXXXXXXXXXXXXX

Brand Name:

XXXXXXXXXXXXXXXXXX

Established Pharmacologic Class:

XXXXXXXXXXXXXXXXXX



Find out reported reactions to drugs

Behavior = should start narrowing list as I put characters in the field

Find out reported reactions for drugs:

Please enter medicine name

☐ *Exact*

Submit

Reset

Drug Reaction Result Screen



Behavior = should start narrowing list as I put characters in the field

Reactions reported for drug XXXXXX:

Top 3 drug reactions reported

Severe

Moderate

Mild

(0)

(1)

(0)

Buttons
Click to display details



Find out interesting facts about your medication



Behavior = should start narrowing list as I put characters in the field

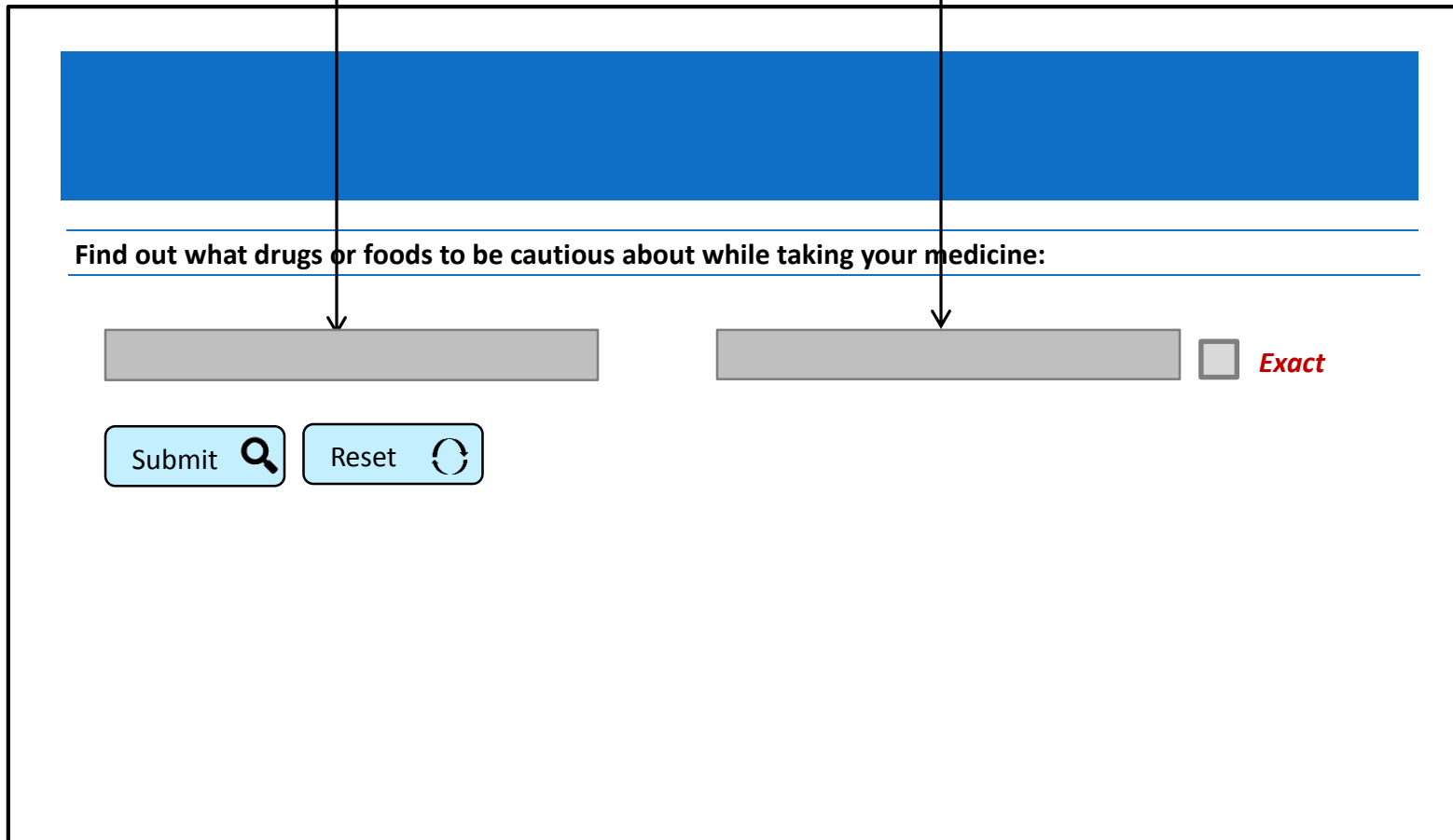
A screenshot of a web form titled "Find out interesting facts about your medication:". The form is enclosed in a black border. At the top, there is a large blue rectangular area. Below it, the title is underlined. The main input section is labeled "Please enter medicine name" and contains a grey text input field. To the right of the input field is a checkbox labeled "Exact" in red text. Below the input field are two buttons: "Submit" with a magnifying glass icon and "Reset" with a circular arrow icon. A vertical black arrow points from the text "Behavior = should start narrowing list as I put characters in the field" to the input field.

[illegible]

Drug to Food Interactions



Behavior = should start narrowing list as I put characters in the field



The screenshot shows a web form titled "Find out what drugs or foods to be cautious about while taking your medicine:". It features two input fields, a "Submit" button with a magnifying glass icon, a "Reset" button with a circular arrow icon, and an "Exact" checkbox. Two arrows from the text "Behavior = should start narrowing list as I put characters in the field" point to the input fields, indicating the expected behavior of the search function.

Find out what drugs or foods to be cautious about while taking your medicine:

☐ *Exact*

Medicine and Food Result Screen



Behavior = should start narrowing list as I put characters in the field



Your Medicine XXXX Interacts with Food XXXXXX

Detailed Drug Interaction Report



Click button link to get detailed
Interaction information

Perform Generic Search



Behavior = should start narrowing list as I put characters in the field


Find out what drugs or foods to be cautious about while taking your medicine:


Select a category

Select subcategory

Select a category

☐ *Exact*

Submit 

Reset 



Perform Generic Search

JSON
Query

Results from OpenFDA

Disclaimer: openFDA is a beta research project and not for clinical use. While we make every effort to ensure that data is accurate, you should assume all results are unvalidated.

Last updated: 2015-05-31

Total results: 5

{"meta": {"disclaimer": "openFDA is a beta research project and not for clinical use. While we make every effort to ensure that data is accurate, you should assume all results are unvalidated.",

"license": "<http://open.fda.gov/license>",

"last_updated": "2015-05-31",

"results": {"skip": 0,

"limit": 1,

"total": 5

}

},

"results": [{"set_id": "0b92e0de-cc94-4498-ac25-a3980c6090b3",

"indications_and_usage": ["Uses • temporarily relieves the following cold/flu symptoms: • minor aches and pains • cough • headache • sore throat • sneezing and runny nose • stuffy nose • temporarily reduces fever"]

],