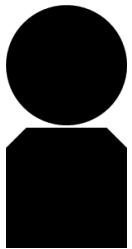


# Consumer Persona



Patient

## Attributes

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

## Goals

- Identify Drug interactions and minimize risk adverse reactions

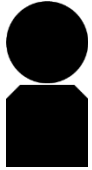
## Concerns

- 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

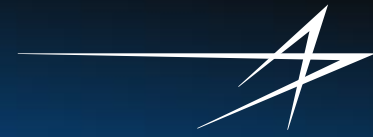
- Pharmaceutical research
- Finds Correlations and patterns in the data

## Concerns

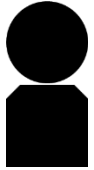
- Comprehensive information
- Accuracy
- Efficiency of Application
- Rapid results

## 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

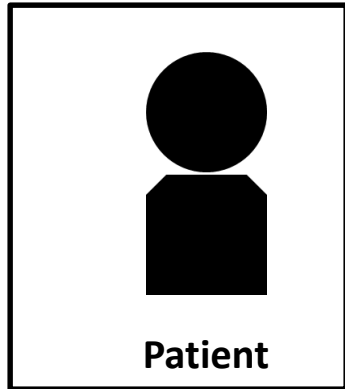
- Comprehensive information
- Accuracy
- Efficiency of Application
- Rapid results

## 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

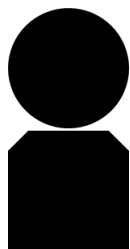
One example is that, Michele Jackson was taking drugs for skin disease, depression, sleeping fovea, etc. Hence he used anesthesia drug used in the surgery to avoid sleeping fovea.

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

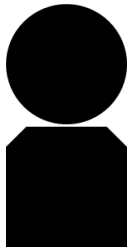
- **Interventions**. When a patient enters the list of medications (drug) he/she currently is currently prescribed in the openFDA website and then using the openFDA data set, interventions must automatically and electronically indicate to a user drug-drug and drug-reaction/warning Adverse Events based 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

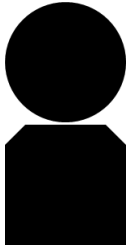
- **Interventions**. When a patient enters the list of medications (drug) he/she currently is currently prescribed in the openFDA website and then using the openFDA data set, interventions must automatically and electronically indicate to a user drug-food and food-reaction/warning Adverse Events based 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



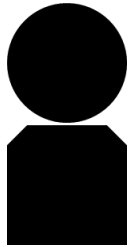
## Use-Case-1 - Drug-Food, Warnings, ask doctor, pregnancy guidelines interaction checks

- **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

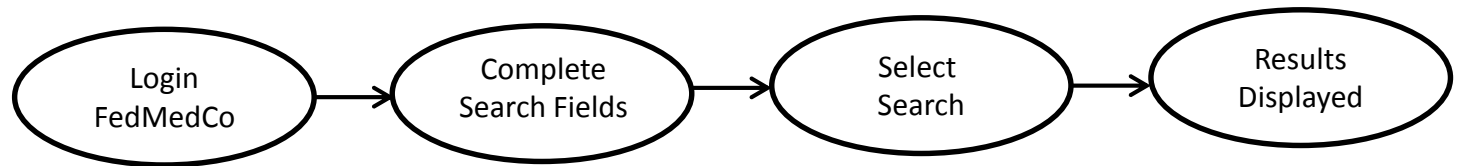
This is a deep dive generic use case where the FDA stakeholders can obtain more information like drug, food, ask doctor, pregnancy guidelines and adverse reaction/warning Adverse Events interactions more information's.

# Scenario Example



Patient

## Common reported drug reactions



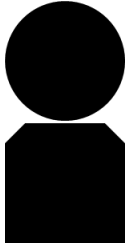
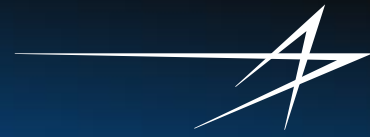
<input generic drug name>

Display top three results in order of likelihood of occurrence.

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

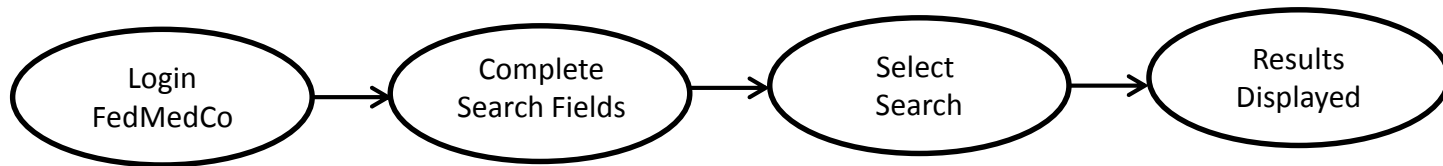


# Scenario Example



Patient

Interesting Facts about you medicine

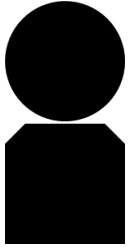


<input generic drug name>

Display:

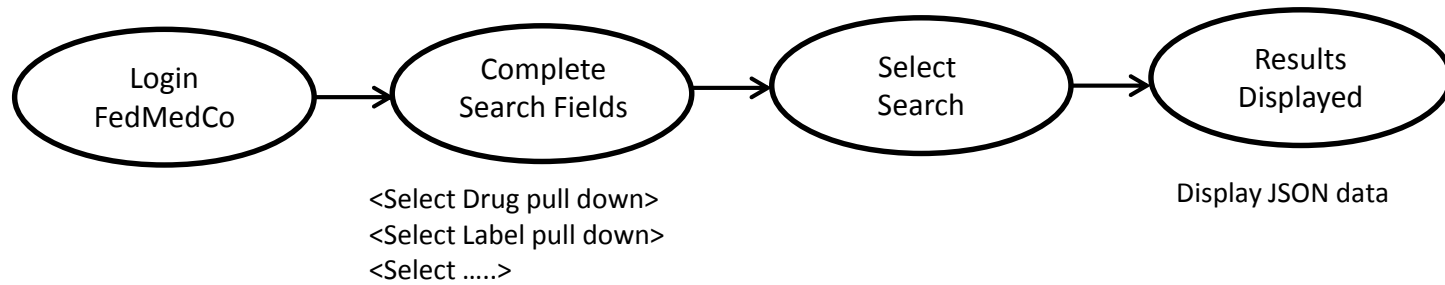
- Purpose
- Stop using If
- Storage and Handling
- What to ask Doctor
- Warnings

# Scenario Example



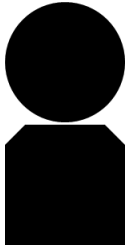
Pharmaceutical  
Manufacturer  
Representative

Open FDA Search



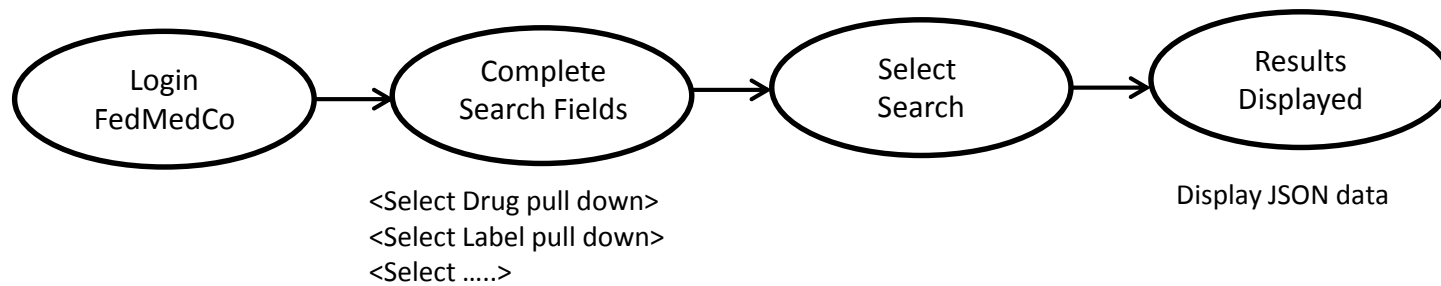
Display JSON data

# Scenario Example



Regulatory  
Professional

Open FDA Search



Display JSON data

# Find out names for your medication



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

Find out all names for your medicine

Medication

☐ *Exact*

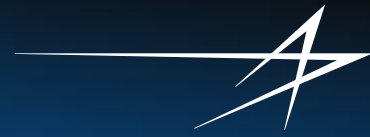


# Name for Medicines Result Screen

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

<hr/>	
All known names for Drug XXXXXXXX <hr/>	
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*

# 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

Buttons  
Click to display details

# Find out interesting facts about your medication



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

**Find out interesting facts about your medication:**

Please enter medicine name

☐ *Exact*



[illegible]

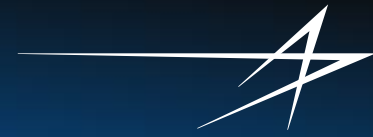
# Drug to Food Interactions



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:". Above the form is a large blue rectangular area. Two vertical arrows point from the text "Behavior = should start narrowing list as I put characters in the field" to the input fields. The first arrow points to a grey input field on the left, and the second arrow points to a grey input field on the right. To the right of the second input field is a checkbox and the word "Exact" in red. Below the input fields are two buttons: "Submit" with a magnifying glass icon and "Reset" with a circular arrow icon.

# 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

## 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"]

],

JSON  
Query