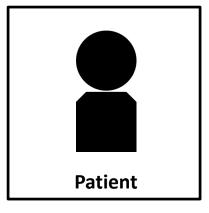
### Consumer Persona





#### **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**

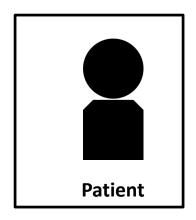
- Consistent use
- Verify products are compliant with regulatory policy and procedures





### 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.

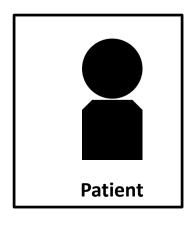
This is a great value add to the FDA agency and a great value proposition/ROI for openFDA.





### Use Case 1 − Drug → Drug Adverse Reactions





#### <u>Use-Case-1</u> - <u>Drug-drug, drug-adverse events interaction checks</u>

- 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 <u>severity level</u> (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





#### <u>Use-Case-1</u> - <u>Drug-drug, drug-adverse events interaction checks</u>

- 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 <u>severity level</u> (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





#### <u>Use-Case-1</u> - <u>Drug-Food, Warnings, ask doctor, pregnancy guidelines interaction checks</u>

• <u>Interventions</u>. 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.

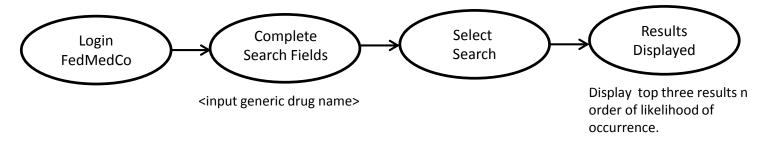








### Common reported drug reactions



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

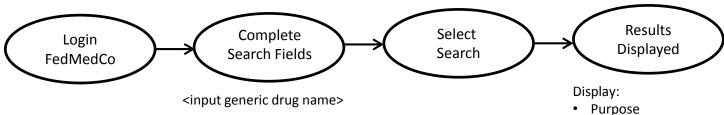








Interesting Facts about you medicine



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



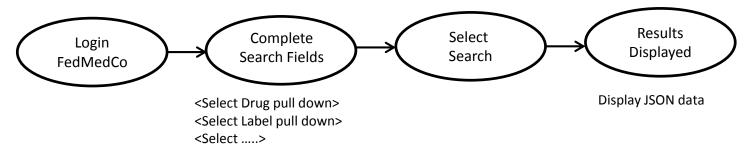






Open FDA Search

Pharmaceutical Manufacturer Representative





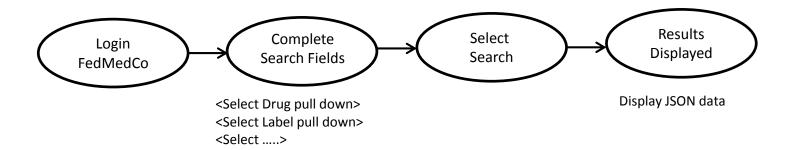






Open FDA Search

Regulatory Professional







# Find out names for your medication



Find out all names	or your medicine		
Medication	Ψ		
Medication		<b>Exact</b>	
Submit <b>Q</b>	Reset (		





### Name for Medicines Result Screen



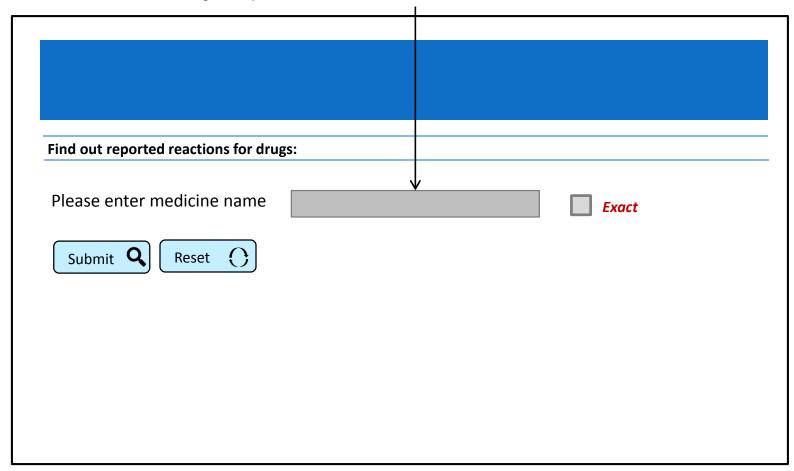
II known names for Drug XXXXXXX		
Generic Name:	XXXXXXXXXXXX	
Brand Name:	xxxxxxxxxx	
Established Pharmacologic Class:	XXXXXXXXXXXXX	





## Find out reported reactions to drugs





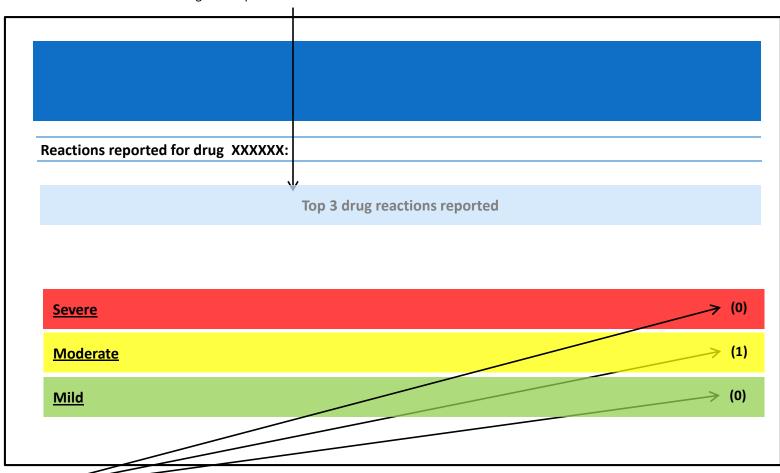




### Drug Reaction Result Screen



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



Buttons
Click to display details





## Find out interesting facts about your medication



Find out interesting facts about your	medication:	
	$\downarrow$	
Please enter medicine name		Exact
Submit <b>Q</b> Reset ()		





# Interesting Facts about Medication Results



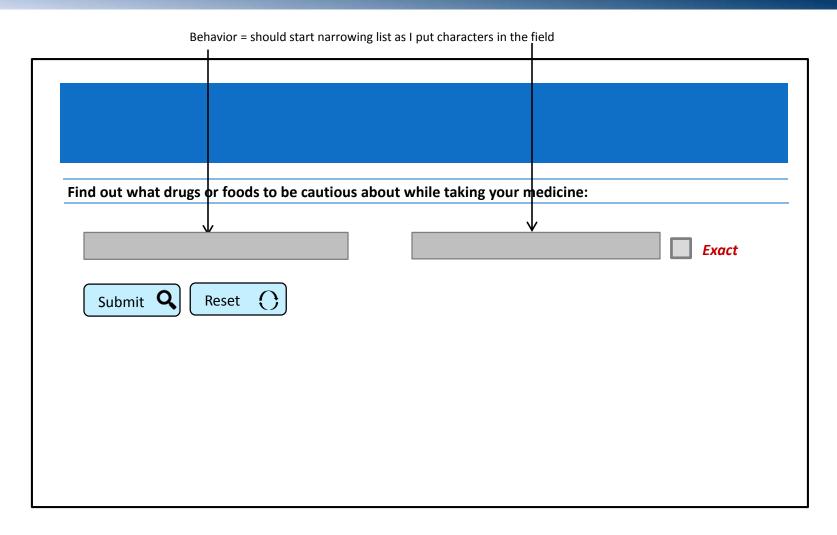
Interesting facts about: XXXXXXX	
	**************************************
Purpose:	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Stop using If:	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Stop using ii.	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Storage and Handling:	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
What to ask doctor:	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Warnings:	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX





## Drug to Food Interactions









# Medicine and Food Result Screen



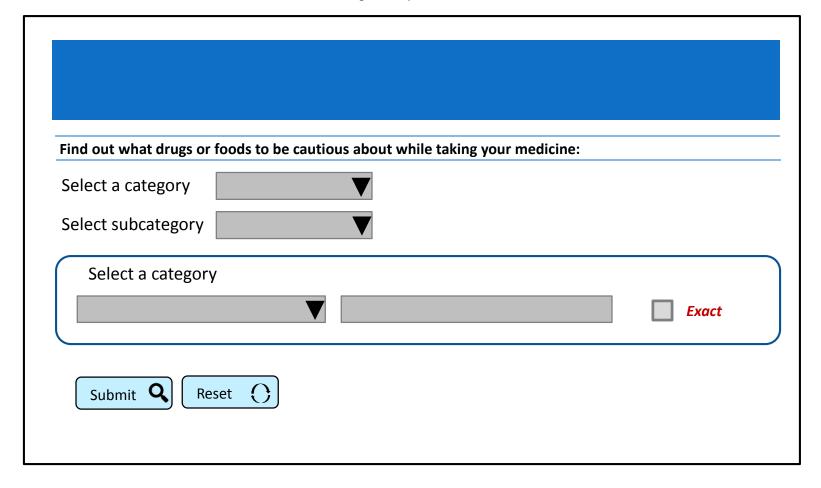
Your Medicine XXXX Interacts with Food XXXXXX
Detailed Drug Interaction Report
Click button link to get detailed
Interaction information





### Perform Generic Search









### Perform Generic Search



#### **Results from OpenFDA**

🕉 isclaimer: 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

JSON

Query

{"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"



