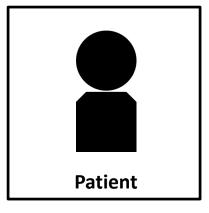
Consumer Persona





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

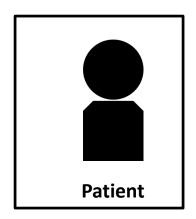
- Consistent use
- Verify products are compliant with regulatory policy and procedures





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

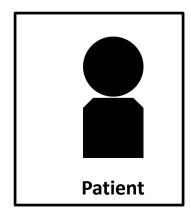
One example is that, Michele Jackson was taking drugs for skin disease, depression, sleeping fovea, etc. Hence he used anesthesia drug used in the surgery to avoid sleeping fovea.

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>

- <u>Interventions</u>. 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











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

• <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.

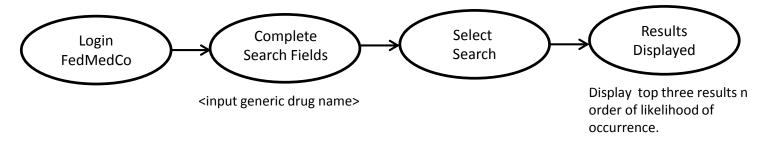








Common reported drug reactions



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



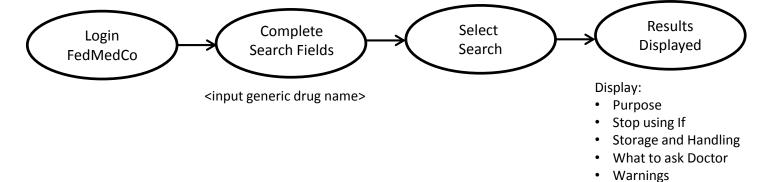






Interesting Facts about you medicine







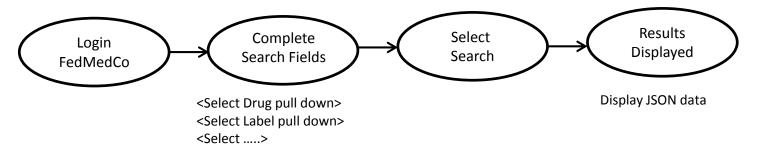






Open FDA Search

Pharmaceutical Manufacturer Representative





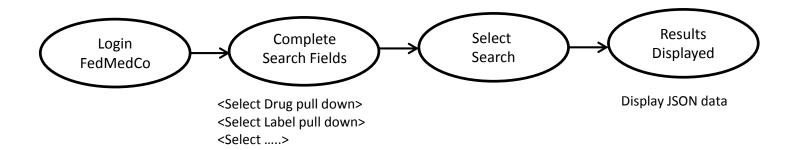






Open FDA Search

Regulatory Professional







Find out names for your medication



Find out all names for your me	edicine		
	V		
Medication		Exact	
Submit Q Reset			





Name for Medicines Result Screen



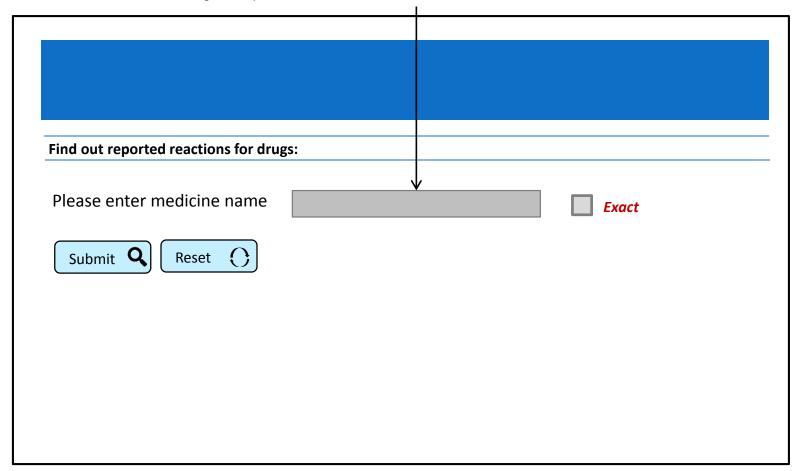
II known names for Drug XXXXXXX		
Generic Name:	XXXXXXXXXXXX	
Brand Name:	xxxxxxxxxxx	
Established Pharmacologic Class:	XXXXXXXXXXXXX	





Find out reported reactions to drugs





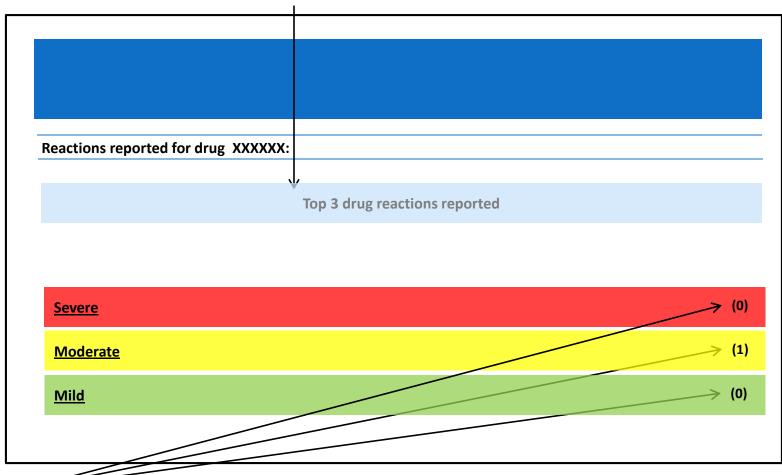




Drug Reaction Result Screen



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



Buttons
Click to display details

LOCKHEED MARTIN

ENGINEERING



Find out interesting facts about your medication



Find out interesting facts about you	r medication:			
	,	V	_	
Please enter medicine name			Exact	
			_	
Submit Q Reset C				





Interesting Facts about Medication Results



Interesting facts about : XXXXXXX	

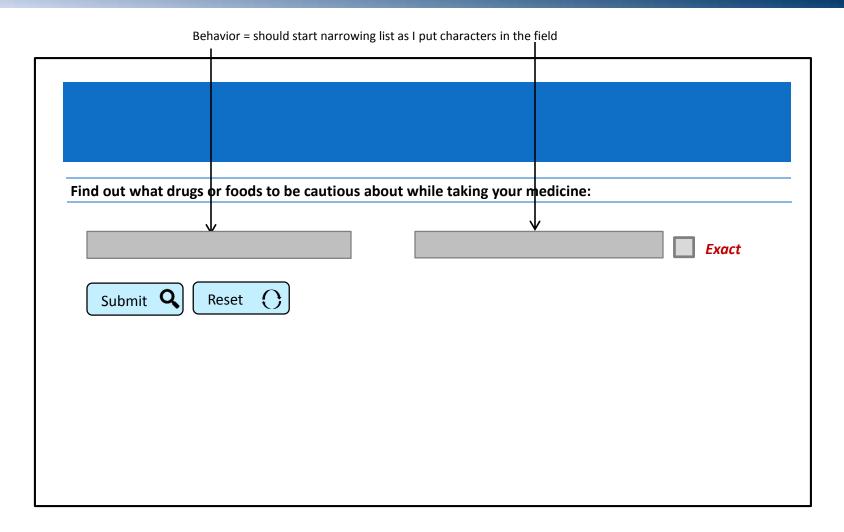
Purpose:	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Stop using If:	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
0	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Storage and Handling:	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
What to ask doctor:	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
What to ask doctor.	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Mounings	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



Find out what drugs or foods to be cautious about while taking your medicine:	
Select a category	
Select subcategory	
Select a category	
	Exact
Submit Q 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

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"

],



