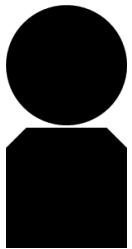


Consumer Persona



Patient

Attributes

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

Goals

- Identify Drug interactions and minimize risk adverse reactions

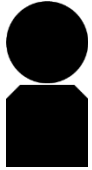
Concerns

- 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

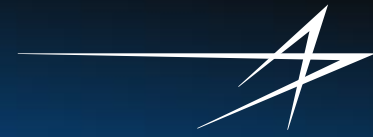
- Pharmaceutical research
- Finds Correlations and patterns in the data

Concerns

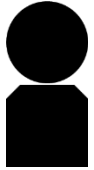
- Comprehensive information
- Accuracy
- Efficiency of Application
- Rapid results

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

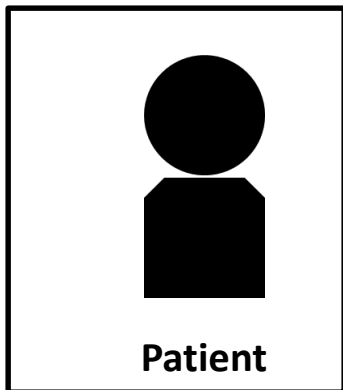
- Comprehensive information
- Accuracy
- Efficiency of Application
- Rapid results

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.

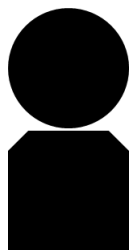
IF openFDA implements Durg→Drug and Drug→Food use case then we could save missions of life's, like Michele Jackson.

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





Use Case 1 – Drug → Drug AE



Patient



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

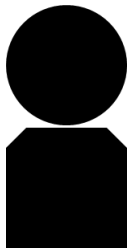
- **Interventions**. When a patient enters the list of medications (drug) he/she currently is currently prescribed in the openFDA website and then using the openFDA data set, interventions must automatically and electronically indicate to a user drug-drug and drug-reaction/warning Adverse Events based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



Patient



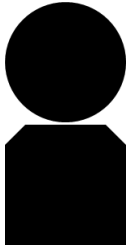
Use-Case-1 - Drug-drug, drug-adverse events interaction checks

- **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



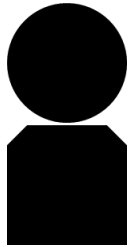
Use-Case-1 - Drug-Food, Warnings, ask doctor, pregnancy guidelines interaction checks

- **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

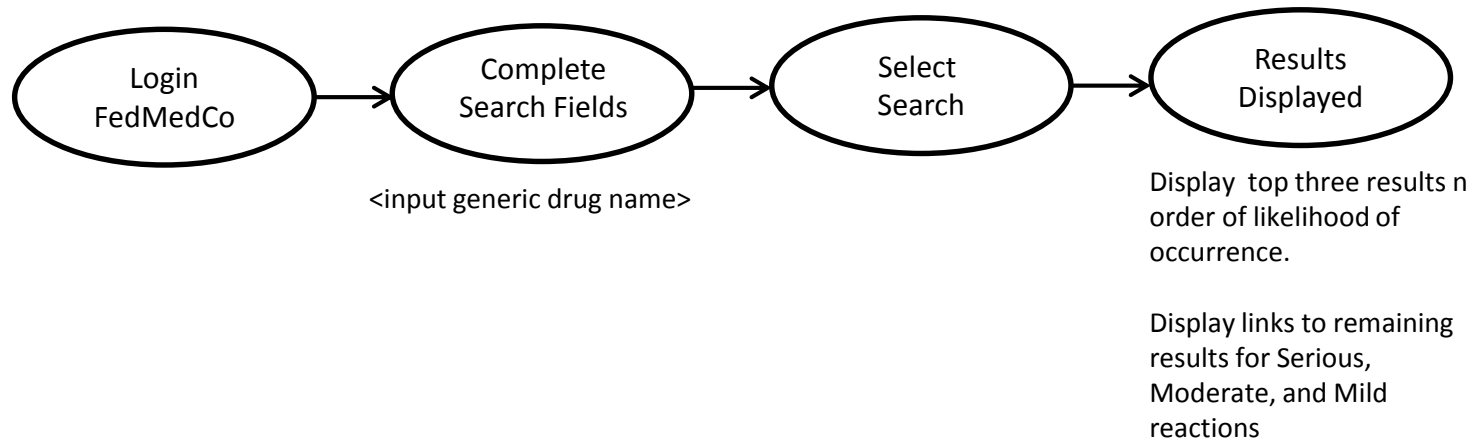
This is a deep dive generic use case where the FDA stakeholders can obtain more information like drug, food, ask doctor, pregnancy guidelines and adverse reaction/warning Adverse Events interactions more information's.

Scenario Example

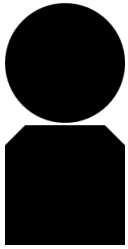
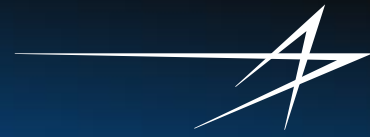


Patient

Common reported drug reactions

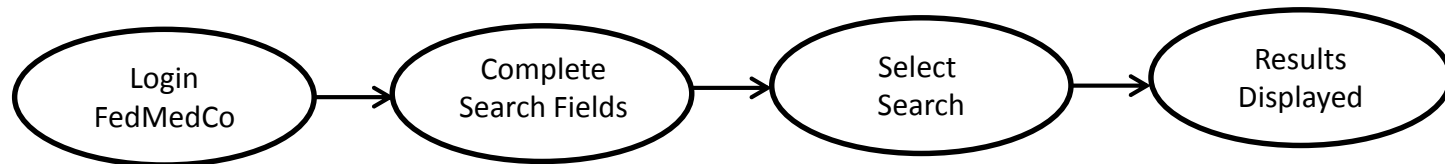


Scenario Example



Patient

Interesting Facts about you medicine

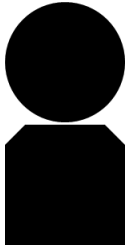


<input generic drug name>

Display:

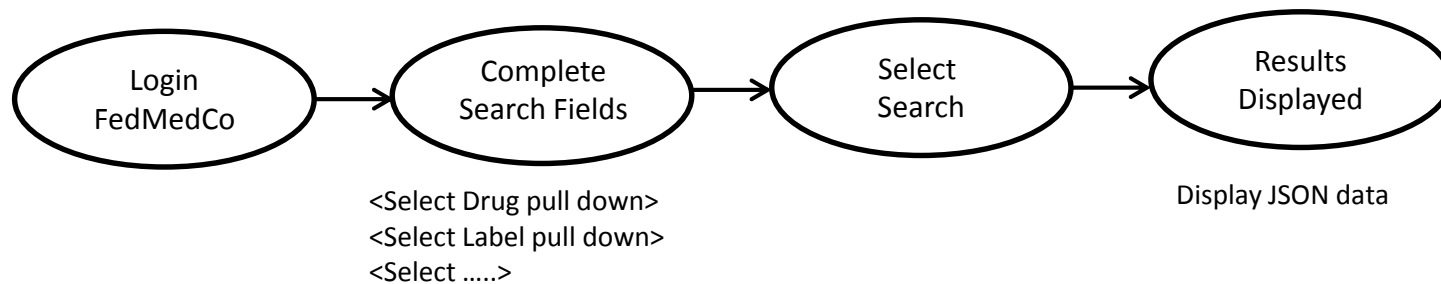
- Purpose
- Stop using If
- Storage and Handling
- What to ask Doctor
- Warnings
- Pregnancy or Breastfeeding

Scenario Example



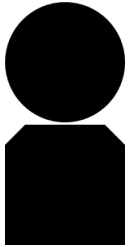
Pharmaceutical
Manufacturer
Representative

Open FDA Search



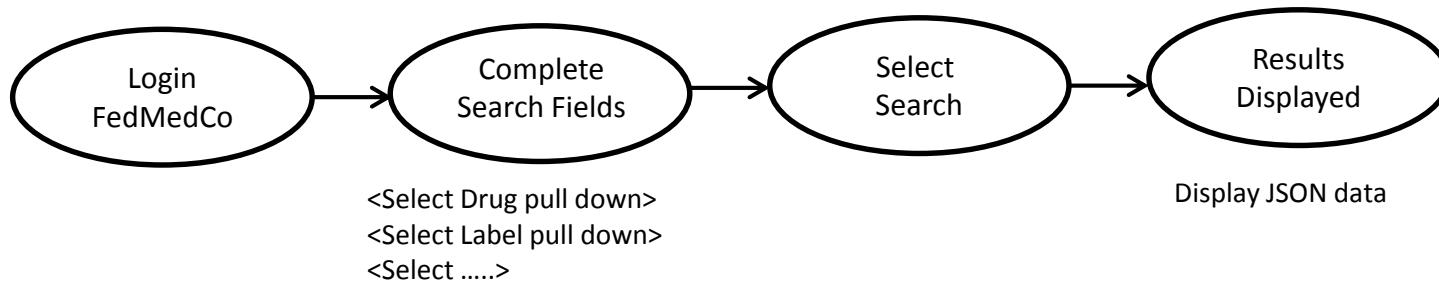
Display JSON data

Scenario Example



Regulatory
Professional

Open FDA Search



[illegible]

LOCKHEED MARTIN
ENGINEERING



Product Canvas



Vision: Deliver Drug and food interaction data to user

Name: 18F Challenge


«Person's Name»

Attributes

- XXXXXXXXXXXXXXXX
- XXXXXXXXXXXXXXXX
- XXXXXXXXXXXXXXXX
- XXXXXXXXXXXXXXXX

Goals

- XXXXXXXXXXXXXXXX
- XXXXXXXXXXXXXXXX
- XXXXXXXXXXXXXXXX
- XXXXXXXXXXXXXXXX

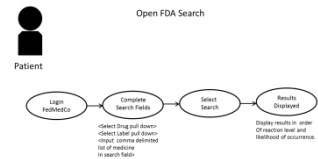
Concerns

- XXXXXXXXXXXXXXXX
- XXXXXXXXXXXXXXXX
- XXXXXXXXXXXXXXXX
- XXXXXXXXXXXXXXXX

Product use and activity

- XXXXXXXXXXXXXXXX
- XXXXXXXXXXXXXXXX
- XXXXXXXXXXXXXXXX
- XXXXXXXXXXXXXXXX

Scenarios



Stories

- Story 1
- Story 2
- Story 3
- Story 4

EPICs

- Prototype
- Submit document
- People

Designs

