## d. Used at least three "human-centered design" techniques or tools

BE employed more than three "human-centered design" tools and techniques by focusing on the needs and wants of BE Safe end users throughout the design and development process. Tools and techniques included (1) end user interviews, (2) personas, (3) sketching, (4) usability testing, and (5) storyboarding. These tools and techniques were included in a cyclical process:

1. Research and Inspiration: Developing personas and conducting end user interviews and market research to identify the business requirements for BE Safe
2. Ideation: Sketching, wire framing, and storyboarding the design using research collected
3. Implementation: Developing the BE Safe website prototype
4. Research: Conducting usability testing and including new findings and designs into the next development sprint

These steps were repeated as often (or in as many sprints) as necessary until the website was deemed ready for release by the Product Owner.

BE has a history of success with human-centered design. At the Department of State's Bureau of Educational and Cultural Affairs (ECA), BE facilitated multiple sessions with designated lead representatives from more than 50 ECA Organizations to establish a standard set of terminology for data capture and reporting. The iterative approach of "human-centered design" marries well with the Agile design and development process for quick feedback and inclusion in the next sprint.

Approach Evidence C discusses our focus on understanding what people need, approach evidence F discusses our usability tests and approach evidence, and approach evidence G discusses our iterative approach where user feedback was considered for subsequent work on the prototype. Approach Evidence C, F, and G are further proof that BE took the time to use more than three human-centered design techniques and tools to understand what people need and included them in the prototype development and design process.

## Human-Centered Design

### *Research: Inspiration Phase*

During the unpacking phase of the Google Venture 5-day model, the team analyzed the business requirements of the OpenFDA solicitation and the datasets from OpenFDA for brainstorming ideas. A photograph of the Google Venture 5-day model is below.

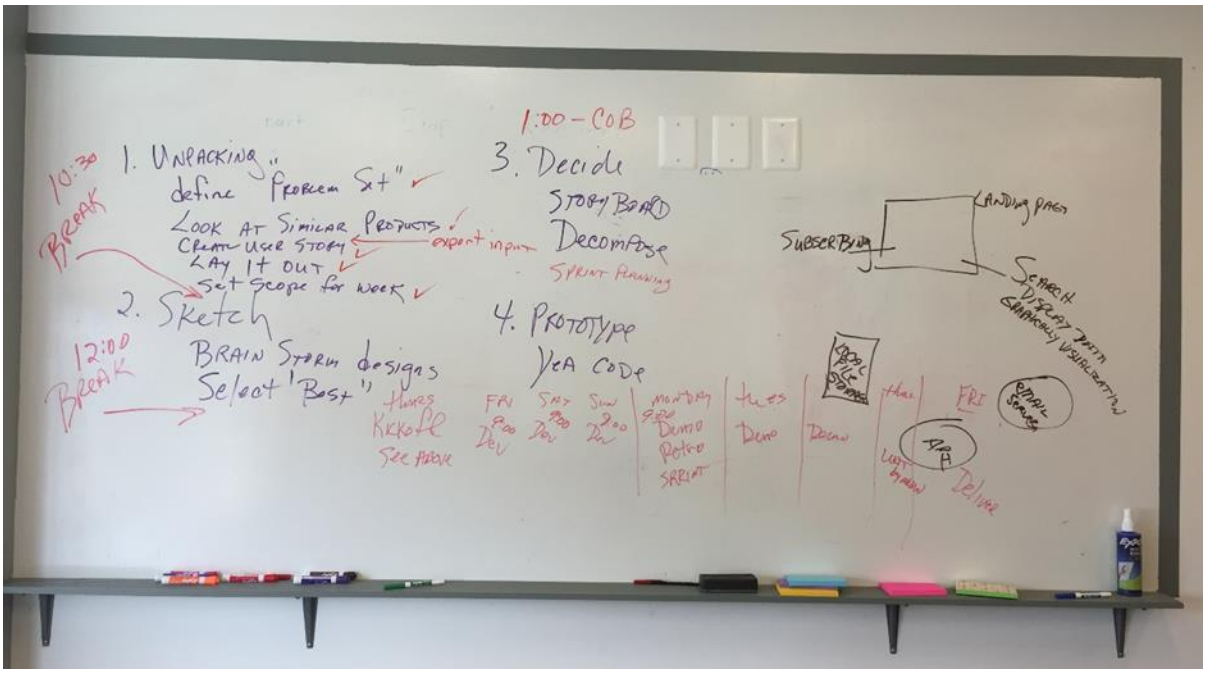


**Figure 1. Google Venture 5-Day Model.**

BE consulted corporate staff who could be representative of fictitious personas by the names of John Q. Public, Kate A. Citizen, Conner S. Consumer, and Sherri M. Caretaker. BE interviewed Dr. Frederick Williams, M.D., FACP (Board certified Internal Medicine) and John Q. Public, Kate A. Citizen, Conner S. Consumer, and Sherri M. Caretaker to identify both the potential user community as well as the target audience. The results of those interviews are captured in Appendix 2 and 3.

Based on Dr. Williams' feedback on the value of the OpenFDA data to clinical physicians, the team decided to build our website to meet the needs and wants of John Q. Public, Kate A. Citizen, Conner S. Consumer, and Sherri M. Caretaker by creating a website that lets users look at drug labels, interactions, and recalls. We also looked at similar products such as Epocrates to ascertain gaps and opportunities to advance the distribution of this type of data.

## *Ideation Phase*

During the ideation phase, BE conducted sketching, storyboarding, and decomposition of the storyboards into epics and user stories during the BE 18F Initial Planning Meeting. BE leveraged our Agile Scrum processes and the Google Ventures 5-Day Model to begin this prototype. The team sketched multiple design concepts and came up with a prototype plan. Six different design sketch artifacts are captured below.

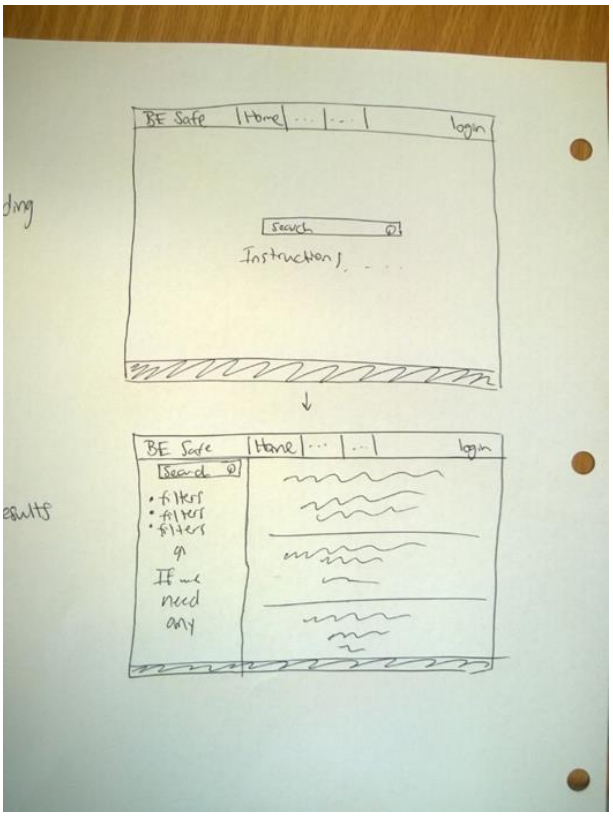


**Figure 2. Prototype Design Option 1**

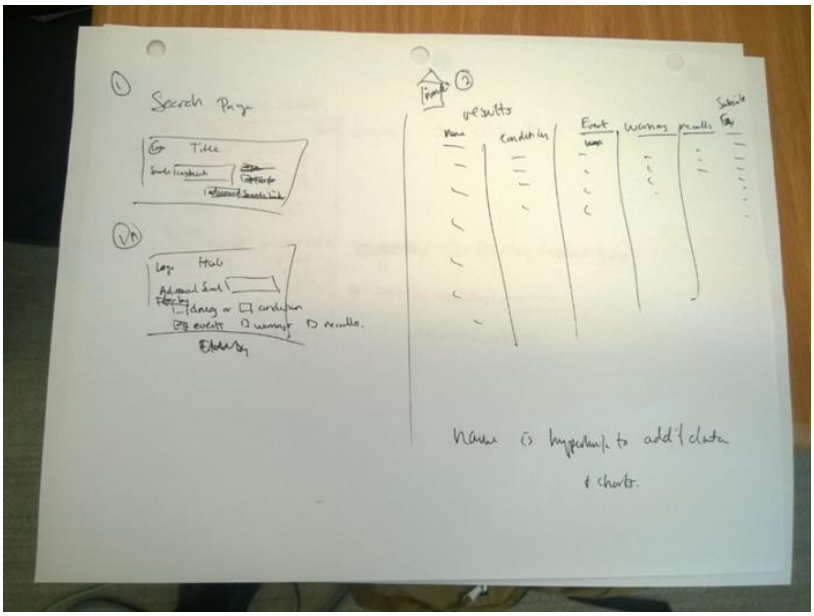


**Figure 3. Prototype Design Option 2**

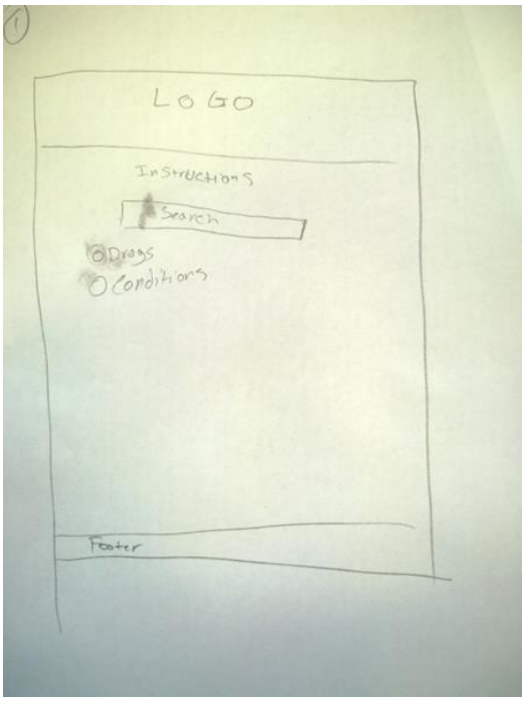


**Figure 4. Prototype Design Option 3, Part 1**

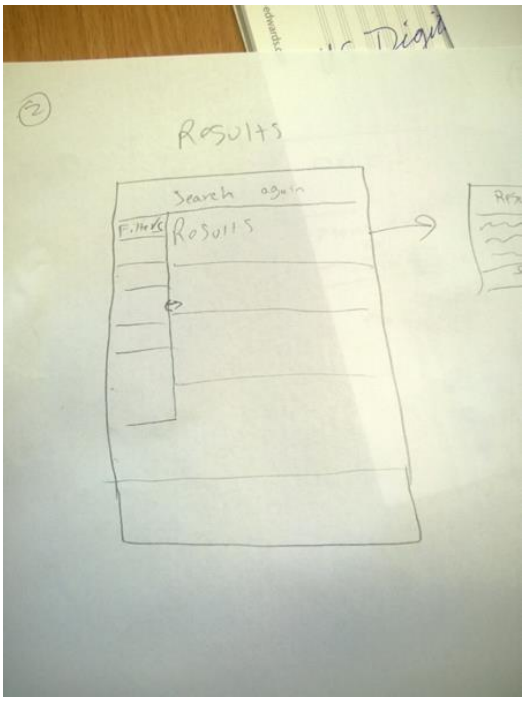


**Figure 5. Prototype Design Option 3, Part 2**

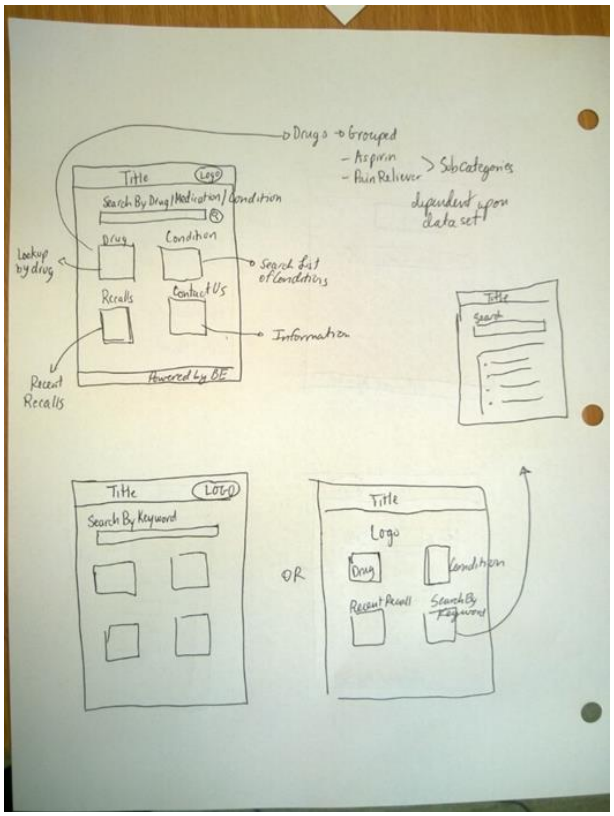


**Figure 6. Prototype Design Option 4, Part 1**

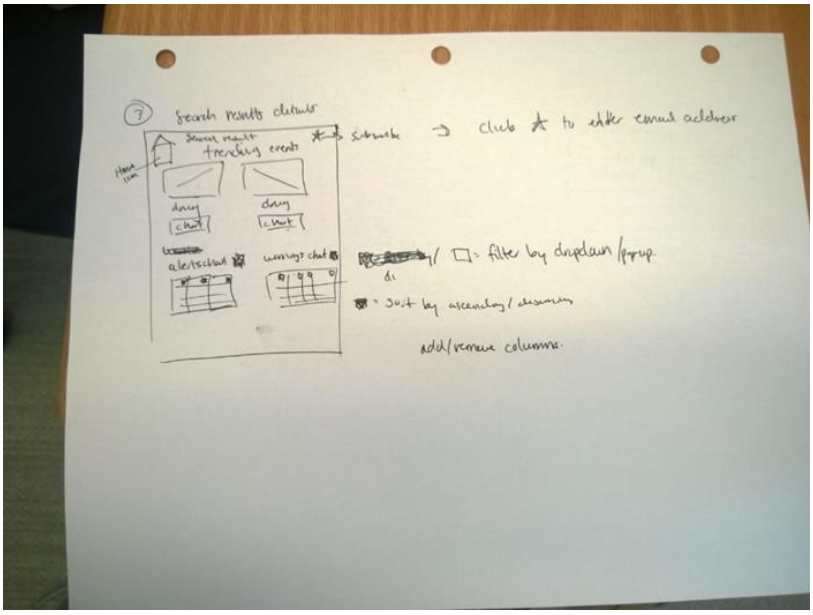


**Figure 7. Prototype Option 4, Part 2**

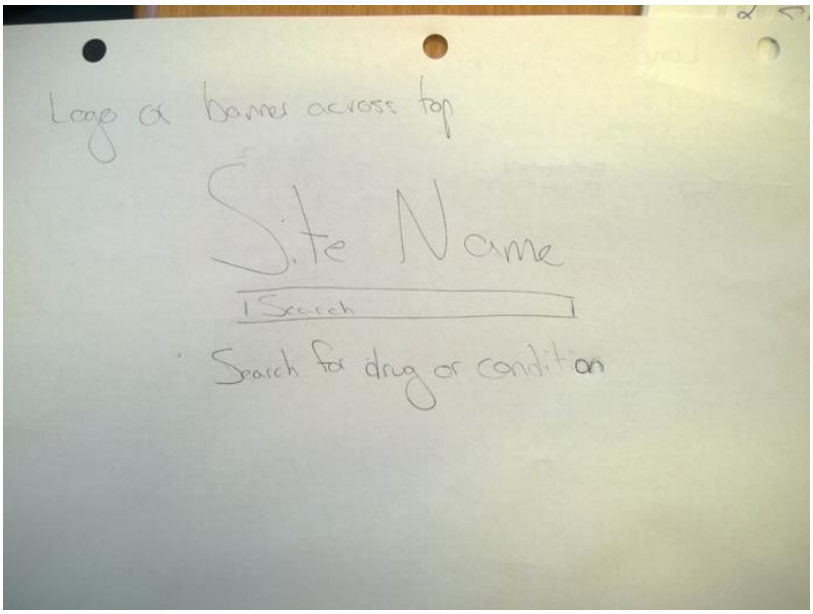


**Figure 8. Prototype Design Option 5, Part 1**

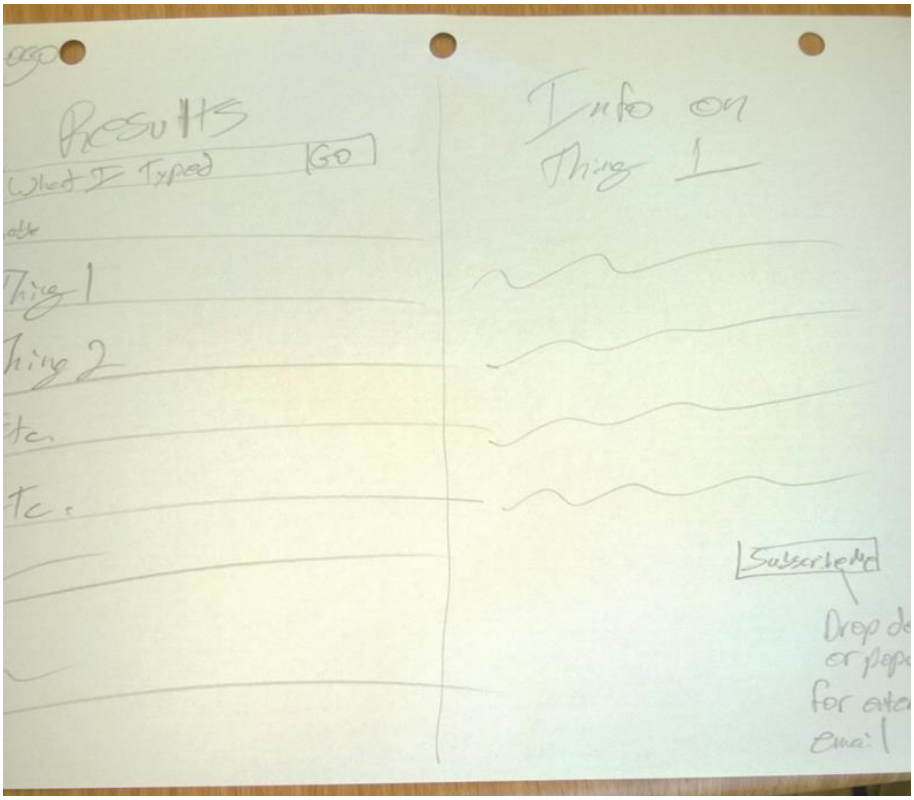


**Figure 9. Prototype Design Option 5, Part 2**

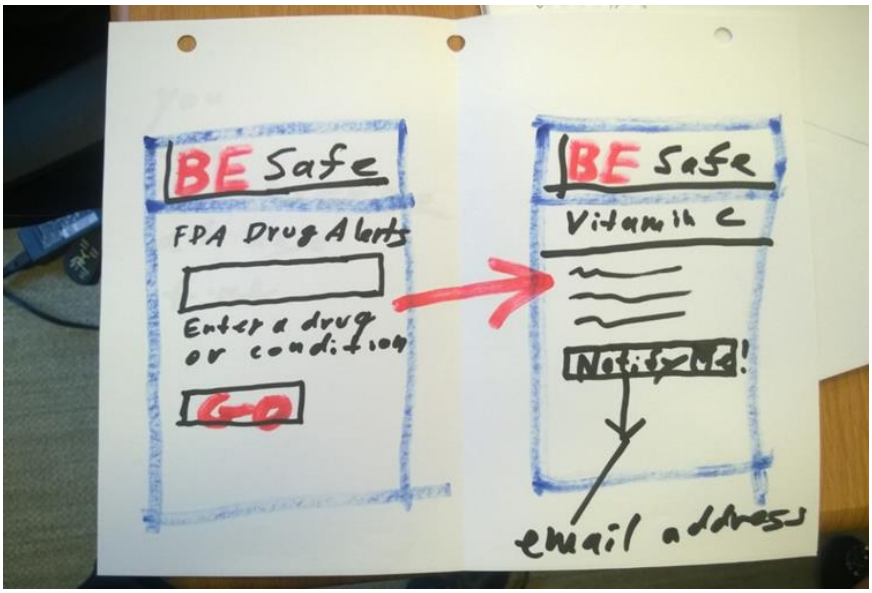


**Figure 10. Prototype Design Option 6**

After discussing design features, the team decided to use a combination of the design sketches presented. The resulting design concept was mocked-up as wireframes and storyboarded on the whiteboard to modify easily. An image of the whiteboard is below.

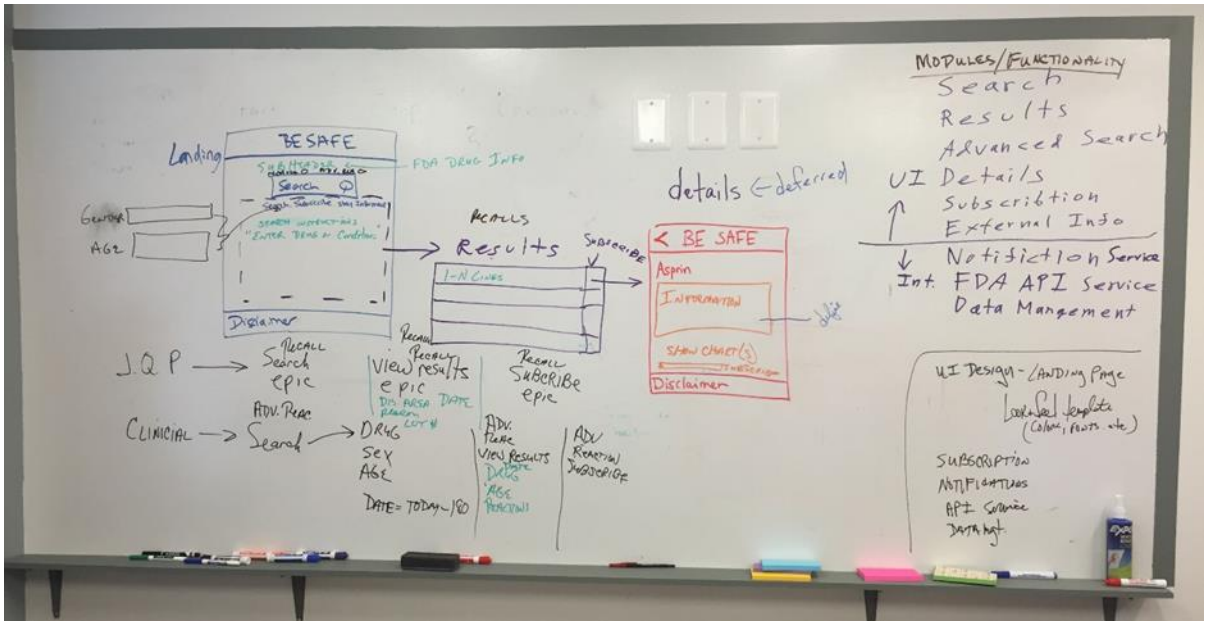


**Figure 11. Prototype Design Concept Mock-Up on Whiteboard**

BE decomposed the storyboard into functional user stories. A photo of the user stories on the whiteboard is provided below.

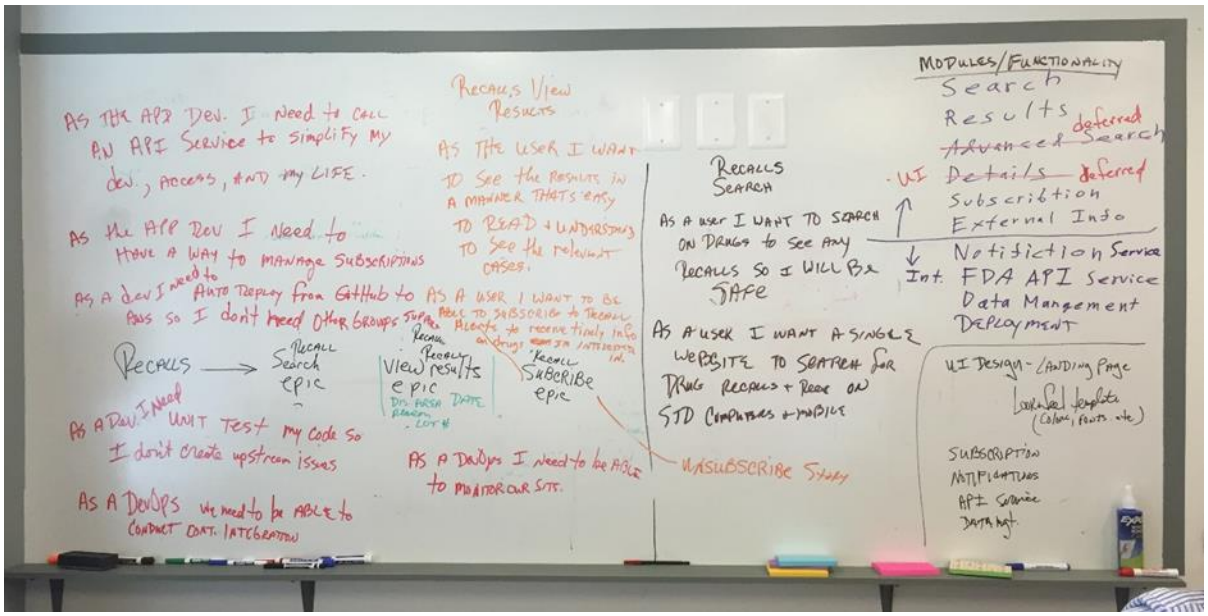


**Figure 12. Decomposition of Storyboard into User Stories**

The meeting minutes from the 18F Initial Planning Meeting are in Appendix 1 below.

## *Implementation Phase*

During the Implementation Phase, BE developed a prototype based on the flushed-out user stories and tasks defined during the Ideation Phase. Using an iterative Agile approach, BE Safe was developed over multiple short sprints.

Approach Evidence G discusses our iterative approach to the implementation.

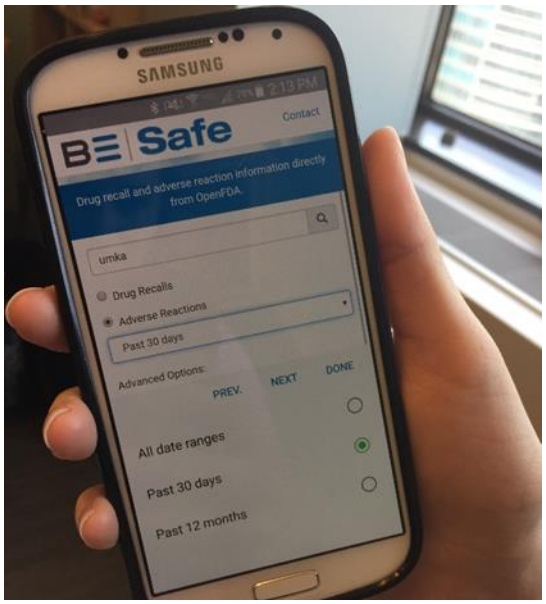


**Figure 13. Mobile View of Prototype**

## *Research: Usability Testing Phase*

BE conducted usability testing with end users unaffiliated with the BE Safe project during Sprint 3. Results of Usability Tests were logged in the Product Backlog in JIRA for prioritization and selection for the upcoming sprint. If selected by the Product Owner, Brian Shafer, the team incorporated a new Ideation Phase and Implementation Phase into the next development sprint(s). See details of Usability Testing in Evidence Approach F.

The following image is a photo reflecting the Results and Analysis step from Sprint 3 usability testing.

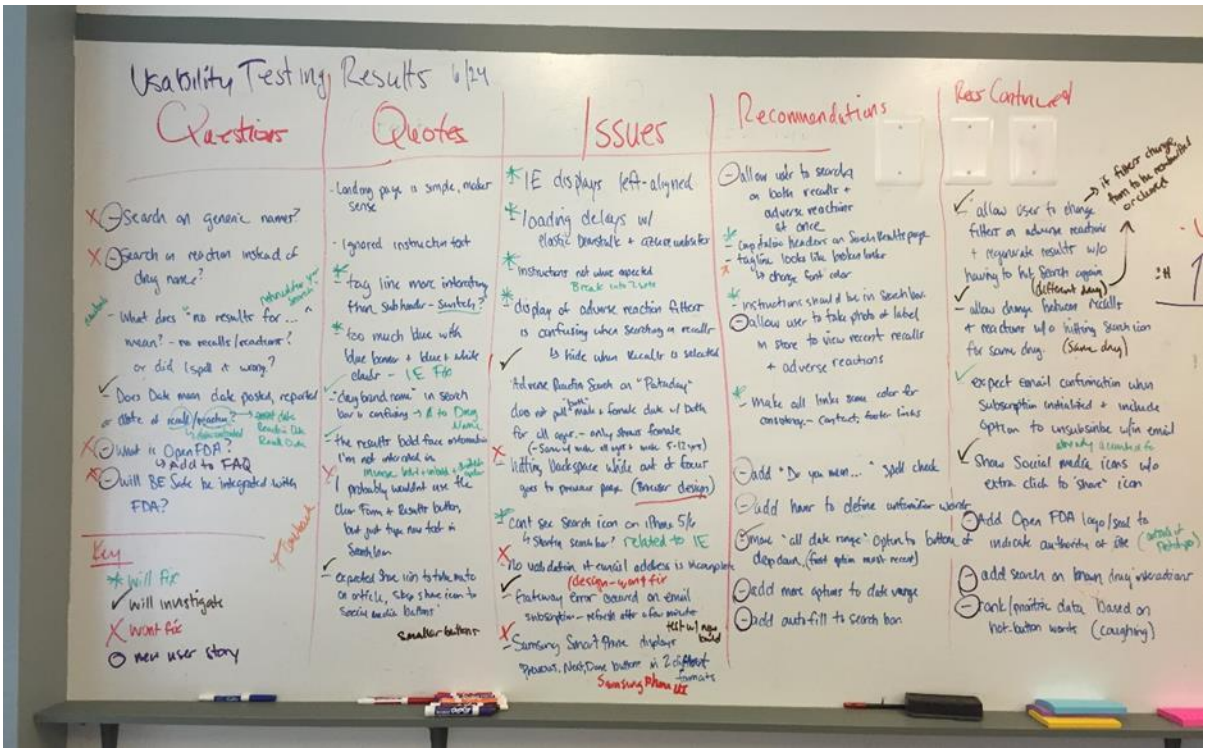


**Figure 14. Sprint 3 Usability Testing Analysis**

The results were then added to the JIRA product backlog for traceability and prioritization.

JIRA Dashboards Projects Issues Agile Create Search

**Usability** — Edited Save Details ★ Export Tools

be.gsa-18f Type: All Status: All Assignee: All Contains text More Advanced
Label: Usability-Test-Results

1–27 of 27 Columns

| T | Key | Summary | Epic Link | Assignee | Created | Fix Version/s | Labels | P | Resolution | Sprint | Status |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | BEG-103 | IE displays app in desktop view as left-aligned | Pharmaceutical Consumer Epic | Frank Hellwig | 24/Jun/15 | 1.0 | Frontend Usability-Test-Results | * | Fixed | Sprint 3 - Prototype, Sprint 4 - Prototype | DONE |
| | BEG-104 | Load delays | Application Developer Epic | Frank Hellwig | 24/Jun/15 | 1.0 | Usability-Test-Results | * | Fixed | Sprint 3 - Prototype, Sprint 4 - Prototype, Sprint 5 - Prototype | DONE |
| | BEG-105 | Text Changes to UI labels/headers | Pharmaceutical Consumer Epic | Frank Hellwig | 24/Jun/15 | 1.0 | Frontend Usability-Test-Results | * | Fixed | Sprint 3 - Prototype, Sprint 4 - Prototype, Sprint 5 - Prototype | DONE |
| | BEG-106 | Hide Adverse Reaction filters when Recalls is selected | Pharmaceutical Consumer Epic | Frank Hellwig | 24/Jun/15 | 1.0 | Frontend Usability-Test-Results | * | Fixed | Sprint 3 - Prototype, Sprint 4 - Prototype | DONE |
| | BEG-107 | Search icon not visible on iOS mobile during/after editing search text | Pharmaceutical Consumer Epic | Frank Hellwig | 24/Jun/15 | | Usability-Test-Results | * | Unresolved | | NEW |
| | BEG-108 | No Validation on Email Address in Subscription pop-up | Pharmaceutical Consumer Epic | Brandt Heisey | 25/Jun/15 | 1.0 | Usability-Test-Results | * | Unresolved | Sprint 5 - Prototype | RESOLVED |
| | BEG-109 | Search a drug for both Recalls and Adverse Reactions in 1 search query | Pharmaceutical Consumer Epic | Brian Shafer | 25/Jun/15 | | Backend Frontend Usability-Test-Results | * | Unresolved | | NEW |
| | BEG-110 | Photograph and upload Photos for search queries | Pharmaceutical Consumer Epic | Brian Shafer | 25/Jun/15 | | Backend Frontend Usability-Test-Results | * | Unresolved | | NEW |
| | BEG-111 | Add auto-fill to search bar | Pharmaceutical Consumer Epic | Brian Shafer | 25/Jun/15 | | Backend Frontend Usability-Test-Results | * | Unresolved | | NEW |
| | BEG-112 | Update date range field | Pharmaceutical Consumer Epic | Frank Hellwig | 25/Jun/15 | 1.0 | Frontend Usability-Test-Results | * | Fixed | Sprint 5 - Prototype | DONE |
| | BEG-113 | Add hover-text on medical terms | Pharmaceutical Consumer Epic | Brian Shafer | 25/Jun/15 | | Frontend Usability-Test-Results | * | Unresolved | | NEW |
| | BEG-114 | Change on Filters Does Not Prompt New Search for same drug | Pharmaceutical Consumer Epic | Brian Shafer | 25/Jun/15 | | Frontend Usability-Test-Results | * | Unresolved | | REJECTED |
| | BEG-115 | Search on reaction term(s) | Pharmaceutical Consumer Epic | Brian Shafer | 25/Jun/15 | | Frontend Usability-Test-Results | * | Unresolved | | NEW |
| | BEG-117 | Subscription Initialization Emails Not Sent for Adverse Reactions | Pharmaceutical Consumer Epic | Brandt Heisey | 25/Jun/15 | 1.0 | Usability-Test-Results | * | Unresolved | Sprint 4 - Prototype, Sprint 5 - Prototype | NEW |
| | BEG-120 | Show social media icons w/o having to make an extra click to view them | Consumer Interaction | Brian Shafer | 25/Jun/15 | | Usability-Test-Results | * | Unresolved | | REJECTED |
| | BEG-121 | Add Search on Known Drug Interactions (labels) | Pharmaceutical Consumer Epic | Frank Hellwig | 25/Jun/15 | 1.0 | Usability-Test-Results | * | Unresolved | Sprint 5 - Prototype | NEW |
| | BEG-122 | Move 'All date range' option to the bottom of the dropdown | Pharmaceutical Consumer Epic | Brian Shafer | 25/Jun/15 | | Usability-Test-Results | * | Unresolved | | REJECTED |
| | BEG-123 | AdverseReaction does not pull data for all genders/ages | Pharmaceutical Consumer Epic | Brandt Heisey | 25/Jun/15 | 1.0 | Usability-Test-Results | * | Unresolved | Sprint 4 - Prototype | REJECTED |
| | BEG-124 | Add spell check to search bar | Pharmaceutical Consumer Epic | Brian Shafer | 25/Jun/15 | | Usability-Test-Results | * | Unresolved | | REJECTED |
| | BEG-125 | Search on generic names | Pharmaceutical Consumer Epic | Brian Shafer | 25/Jun/15 | | Usability-Test-Results | * | Unresolved | | DEFERRED |
| | BEG-126 | Add FAQ to BE Safe to define what is OpenFDA | Pharmaceutical Consumer Epic | Brian Shafer | 25/Jun/15 | | Usability-Test-Results | * | Unresolved | | REJECTED |
| | BEG-127 | Reduce the size of the social media icons | Pharmaceutical Consumer Epic | Jefferson Baker | 25/Jun/15 | 1.0 | Frontend Usability-Test-Results | * | Fixed | Sprint 5 - Prototype | DONE |
| | BEG-128 | Backspace while out of focus goes to previous page | Pharmaceutical Consumer Epic | Brian Shafer | 25/Jun/15 | | Frontend Usability-Test-Results | * | Unresolved | | REJECTED |
| | BEG-129 | Gateway Error on email subscription | Pharmaceutical Consumer Epic | Frank Hellwig | 25/Jun/15 | 1.0 | Usability-Test-Results | * | Fixed | Sprint 5 - Prototype | DONE |
| | BEG-130 | Samsung Smart Phone displays two formats of navigation buttons | Pharmaceutical Consumer Epic | Brian Shafer | 25/Jun/15 | | Usability-Test-Results | * | Unresolved | | REJECTED |
| | BEG-131 | Add OpenFDA logo to app | Pharmaceutical Consumer Epic | Brian Shafer | 25/Jun/15 | | Usability-Test-Results | * | Unresolved | | REJECTED |
| | BEG-132 | Rank/Prioritize data based on hot-button words | Pharmaceutical Consumer Epic | Brian Shafer | 25/Jun/15 | | Usability-Test-Results | * | Unresolved | | DEFERRED |

1–27 of 27

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**Figure 15. Sprint 3 Usability Testing Results in JIRA**

### *Iterative Research Phase*

In addition to conducting usability testing, BE reached out to the Product Owner, Brian Shafer to discuss new BE Safe features and business requirements for consumer interaction, specifically the ability to share search results on social media and to notify the FDA of a similar adverse reaction (Me Too).

### *Iterative Ideation Phase*

The team developed new wireframes and storyboarded the consumer interaction concept. An image of the Me Too wireframe is pictured below.

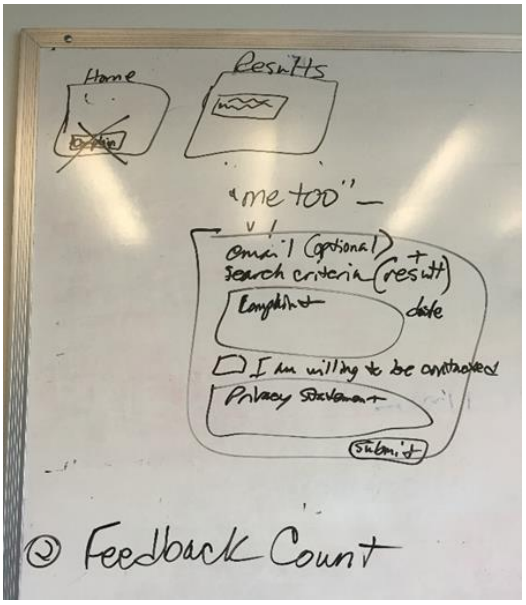


**Figure 16. Consumer Interaction Wireframe**

BE came up with a second iteration of design options and a prototype concept for the new features after breaking the storyboard down into user stories.

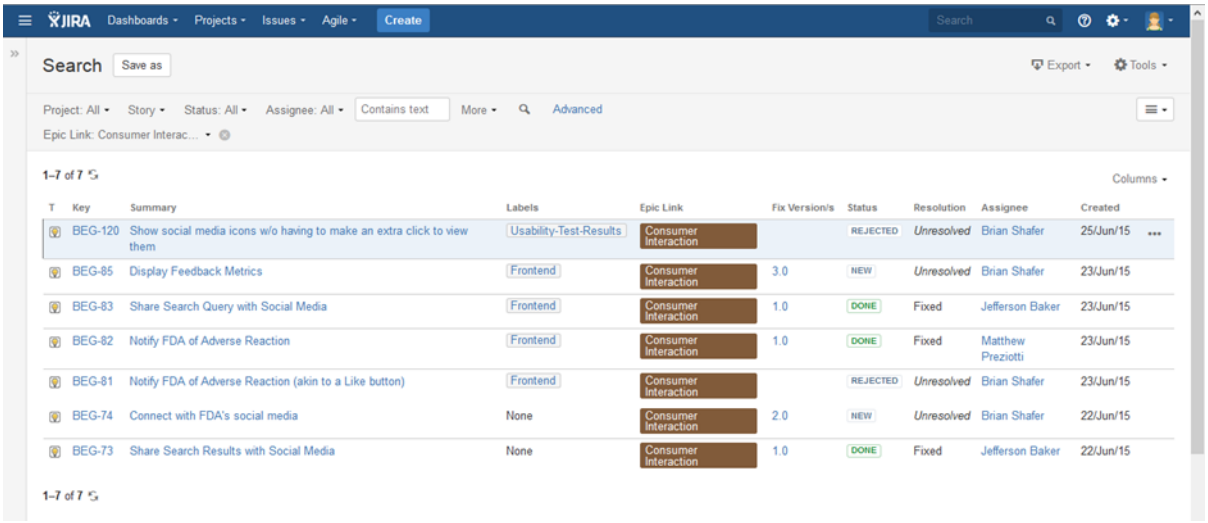


**Figure 17. Consumer Interaction User Stories**

## *Iterative Implementation Phase*

During the Implementation Phase, BE developed a prototype based on the flushed-out user stories and tasks defined during the Ideation Phase. Using an iterative Agile approach, BE Safe was developed over multiple short sprints.

Approach Evidence G discusses our iterative approach to the implementation. Below are screenshots of the Me Too feature in the smartphone view.

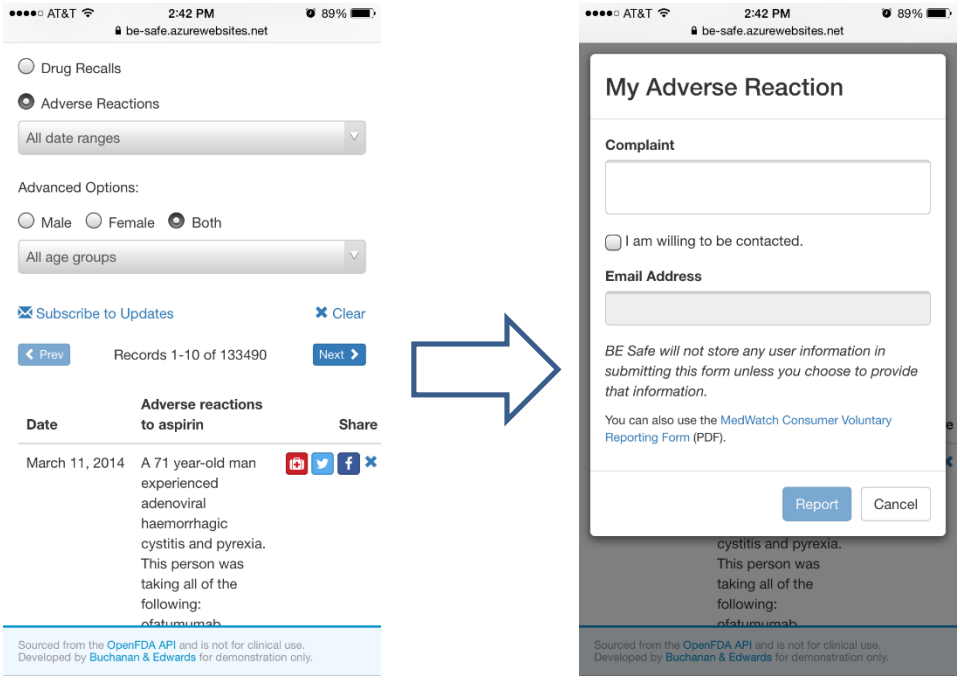


**Figure 18. Implementation of the Me Too Feature on the BE Safe Website**

## *Iterative Research: Usability Testing Phase*

BE conducted usability testing with end users unaffiliated with the BE Safe project during Sprint 6. Results of usability tests were logged in the Product Backlog in JIRA for prioritization and selection for the upcoming sprint.

Below is an image of the results from usability testing entered into the JIRA product backlog.

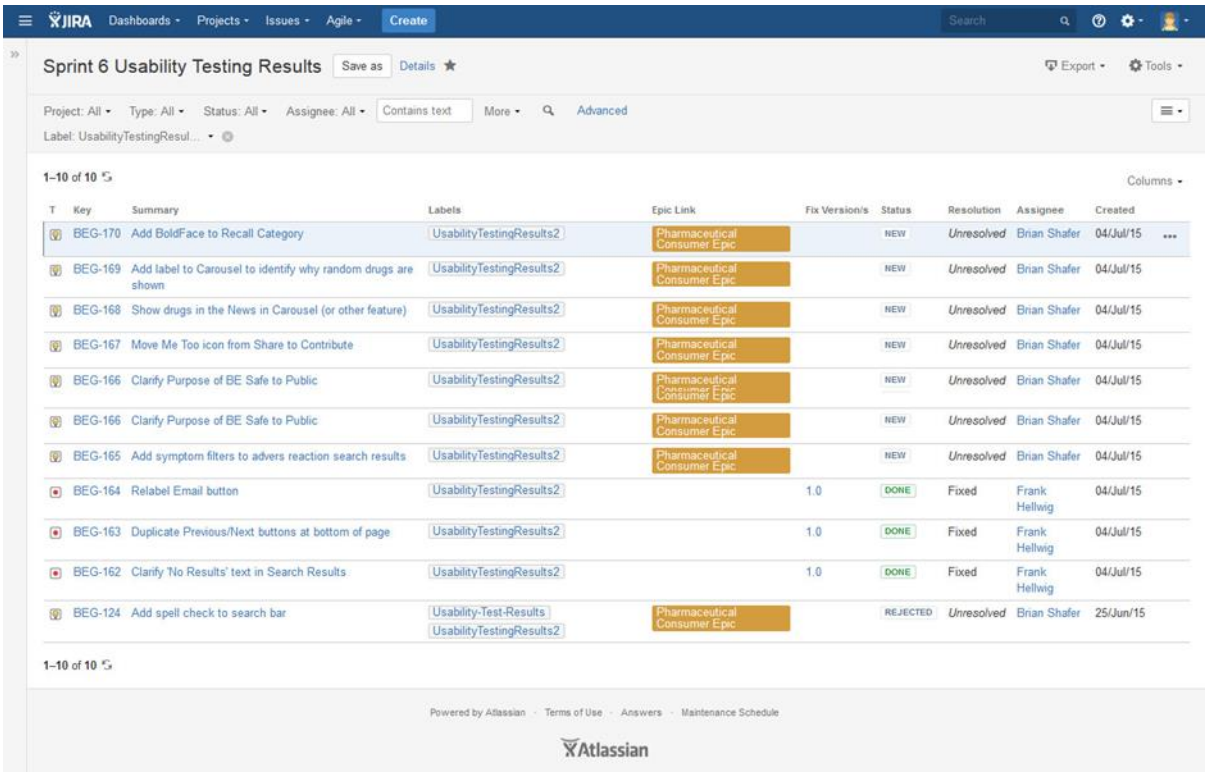


**Figure 19. Sprint 6 Usability Testing Results in Jira**

See details of usability testing in Approach Evidence F.

## Appendix 1 BE 18F Initial Planning Meeting Minutes

| **Meeting Description**: BE 18F Initial Planning Meeting to conduct initial RFQ Planning activities following the Google Venture's 5-Day Design Model approach. Reference Materials: GSA RFQ files | | |
|---|---|---|
| **Date:** 6/18/2015 | **Time:** 9:00 am | **Location:** BE Corporate Office |

| **Participants** | | | | | ***** in attendance, **#** absent, **+** substitute, **%** via phone |
|---|---|---|---|---|---|
| 1 | Brian Shafer | * | 7 | Phil Samra | * |
| 2 | Mike Holt | * | 8 | Matt Preziotti | * |
| 3 | Frank Hellwig | * | 9 | Kelsey Mason | * |
| 4 | Brandt Heisey | * | 10 | Theodore (Tad) Miller | * |
| 5 | Lauren Turbeville | * | | | |
| 6 | Jefferson Baker | * | | | |

| **Agenda** | | **Presented By** | |
|---|---|---|---|
| 1 | Scope of Work and Delivery | | Brian Shafer & Mike Holt |
| 2 | Google Venture 5-Day Design Model<br>• Unpack<br>  ○ Define Problem Set<br>  ○ Review SME feedback<br>  ○ Search similar products<br>  ○ Layout initial design<br>  ○ Scope out activities for week<br>• Sketch<br>  ○ Draw ideas for prototype design<br>  ○ Select Best Design<br>• Decide<br>  ○ Storyboard site<br>  ○ Decompose into user stories<br>• Discuss Topics for Tomorrow | | Mike Holt |

| **Minutes** | |
|---|---|
| 1 | BE Team reviews and discusses RFQ for development and delivery requirements. |
| 2 | Mike steers group to goal of getting to Day 4 of 5 of the Google Venture 5-Day Design Model into 1 day |

| | |
|---|---|
| 3 | "Day 1:" Unpacking – BE Team…<br>• Defines the problem set based on everyone's understanding of the RFQ: need a prototype by 6/26 to 'consume, modify, remix, or display the OpenFDA dataset provided for its functionality.'<br>• Evaluates interview information with John Q. Public, et al personas and Dr. Williams.<br>  ○ Since Dr. Williams sees little value with OpenFDA data, BE Team decides to create prototype with John Q. Public in mind.<br>• Looks at similar products (Epocrates.com, VisualizeFDA)<br>• Identifies a draft product vision and high-level user story for ability to search on (1) alerts on recalls, (2) adverse events related to my medications, and (3) ability to subscribe/unsubscribe to email alerts<br>  ○ BE Team raises concerns about HIPAA violations for collecting personally identifiable information (PII) and decides to treat the email addresses the same as a password.<br>  ○ BE Team discusses displaying graphic representations of the search results, but decides against it with VisualizeFDA site in mind (recognizing it's not a prototype)<br>  ○ BE Team determines datasets are not pretty, so presenting the search results in a user-friendly, consumable display will be important<br>• Creates a high-level site design (layout) on the whiteboard.<br>• Creates a schedule for the week |
| 4 | "Day 2:" Sketching<br>• Each BE Team member sketches his/her own design concepts and presents to the BE Team.<br>  ○ Team discussed what we liked/didn't like for each design<br>  ○ Our "Best" design was easy since most designs were along the same lines.<br>• BE Team agrees to a 'Best' design concept from alternatives:<br>  ○ Headers, footer, logo<br>  ○ Search bar similar to Google and radio buttons to toggle between recalls and adverse reactions. Advanced search criteria of date range is available to both; age range options are only available to adverse reaction searches.<br>  ○ Search results page will display rows of data by date and recall/adverse reaction information<br>  ○ Ability to subscribe to search query available |

| | |
|---|---|
| 5 | "Day 3:" Decide / Sprint Planning Meeting – BE Team…<br>• Storyboards user scenarios<br>  ○ Spends several hours decomposing the requirements into user stories<br>• Defines 2 epics: Pharmaceutical Consumer (UI, email, query data) & Application Developer (continuous integration, continuous monitoring, deployment prep, security)<br>  ○ User stories are entered into JIRA<br>• Defines a number of user stories based on the interviews with John Q. Public<br>  ○ User stories are entered into JIRA and assigns story points/estimation<br>• Defines tasks for each user story<br>  ○ Tasks are entered into JIRA, and assigned to team members |
| 6 | "Day 4:" Prototype<br>BE Team ready to start coding first thing on Friday, 6/19. |
| 7 | Mike addresses plans for Tomorrow (Friday, June 19)<br>• We will conduct an initial user story analysis, refactor as needed.<br>• Conduct a Sprint #1 planning session<br>Kick off Sprint #1 |

| | **Action Items** | **Owner** | **Status** | **Due Date** | **Completion Date** |
|---|---|---|---|---|---|
| 1 | See JIRA for action items in task format | all | Open | 6/22 | 6/22 |

## Appendix 2 Citizen and Healthcare Consumer Personas and Interview Results

John Q. Public is a 54 year-old male and Marine Corp veteran who lives in Wichita, KS with his wife and three kids. He works at the USPS making $58,000 a year to support his family. His wife is a stay at home mom. He takes a cocktail of asthma medications and worries that he may not be aware of all recalls on the market. He is an advocate for privacy and does not discuss his health with anyone but his wife and doctor.

- As a citizen and healthcare consumer, I take multiple medications for asthma. I want to be alerted if there are any recalls of the medications I am currently taking. I want to be able to be alerted if there is a dramatic change in adverse events related to my medications. Ideally, I want to be able to set my sensitivity level to such adverse events based on the volume of mortality and/or severity of reactions. I want to be anonymous-----I don't care if my searched/watched medications profile (sans identifying information) is stored to enable such warnings and alerts so long as nobody knows who I am or can track that data back to me.

Kate A. Citizen is a 20 year-old undergrad student at Clemson University with an interest in supply chain management and healthcare. She is in a work-study program with the women's tennis team. Her dream is to work at the Centers for Disease Control someday and plans to write her thesis on the supply chain and response to drug recalls. She does not want to be affiliated personally with the subjects or content that she researches in a professional context.

- As a citizen and healthcare consumer, I want to be able to see if there are any recalls of a specific medication or warnings of the combination of one or more medications. I want to be able to see recalls of a specific medication graphically along with the history of adverse events over time. I don't want any information stored about me or what medications I research.

Conner S. Consumer is a 78 year-old retired salesman in Philadelphia, PA who enjoys reading the local paper daily and writing letters to the editor. He is an early adopter of all things technology and often has the latest gadgets on the market. When online shopping, he takes the time to read and write reviews on sites like Amazon.com. He enjoys sharing his most recent health woes when asked, "How are you doing?" He recently mixed the wrong dosage of medication and had an adverse reaction that sent him to the hospital for 4 days.

- As a consumer of Pharmaceuticals I have had adverse reactions to medications. I would like to way to know if other people have experienced the same thing. I would also like to let the FDA know that I have experienced the same thing as someone else. I may or may not want the FDA to have my personal information and contact me.

Sherri M. Caretaker is a 39 year-old single mother of two whose son has been diagnosed with Leukemia. She balances her work as an Office Manager with hospital visits with trying to make a normal life for her kids. She is glued to her mobile devices, often working remotely while tending to her children's busy schedules. She uses Facebook and Twitter to stay up to date with friends and family as well as local and national support groups and to keep tabs on current events. She frequently posts her experiences and new articles to Facebook and Twitter.

- As a caretaker for a family member on a complex medication regimen, I want to be able to share relevant drug recalls and adverse reactions with my network that I find interesting or informative.

## Appendix 3 Clinical Physician Interview Results

Source: Dr. Frederick Williams, M.D., FACP (Board certified Internal Medicine)

- As a clinical physician caring for patients, the only time I would use the OpenFDA adverse event data would be in rare cases where a patient is suspected to be having a drug interaction that is not published through the normal tools. I could perhaps envision searching such data to see if one or more drugs were related to an adverse event similar to my patient's. Such a search might be in addition to or instead of a PubMed search to look at case history reports. However, this would happen rarely and clinicians such as myself rely on the data and tools that reflect the latest published findings on a drug. Also, I would not rely on it given the FDAs warning that it should not be used for clinical purposes. Applications such as Epocrates and others provide me with drug interactions, dosaging, side effects and other data that I currently rely on.
- As a physician, I look for possible drug interactions (included in structured product labeling?) when seeing a patient/reviewing their list of medications and before prescribing a new medication. I also look for common and serious side effects to advise the patient on what they might experience. I want to see the most common side effects first as reported via the published data, not every adverse event which might be of use to a researcher. I also want to see the most serious side effects. I must translate those side effects into a language laypeople can understand. To use the OpenFDA data, I would need to trust it for clinical use.
- As a physician, it would be an added feature if drug recall data could be compared to my Electronic Medical Records (EMR) for my patients to alert me to any recalls impacting my patients.

**Answers to Discovery Questions**

- *How would you use this type of information?* Possible use cases are listed above. What makes the usage limited for me includes the following: not for clinical use, don't have time to pour over lists of possible adverse events when the published literature and tools (mobile apps, etc.) can zero in on what is important. The structured product labeling appears to have the information (e.g. drug interactions, side effects) that I most use today, although I get it from existing commercial products and apps such as Epocrates. Recall data is certainly important, but not if I have to pour through the EMR every time a recall comes out.
- *What about this information is interesting in your line of work?* If the information can be prioritized and presented to me in an easily consumable way. If the information could be translated from medical jargon to something a layperson understood, it might be interesting to a non-medical person.
- *Is this most valuable to people in a specific industry or with specific skills and experience or does it also have value to the general public?* The data is probably useful to researchers. If the adverse events and drugs are described with both medical jargon and terms, then it is less useful to the general public. They would need their physician to translate.