# Sprint Planning

As part of Sprint Planning, the Product Manager, Front End Web Designer and Interaction Designer/User Researcher/Usability Tester identified a preliminary set of data, tooling and support tasks for addressing the Prioritized Product Backlog from a design perspective, starting with Epic 1. An initial decision was made to leverage Pentaho, an open source visualization component. The key design constraint influencing this decision was the apparent RFQ requirement to access data for the Design Prototype using the Open FDA API. This was an important factor because the team had extensive experience with Tableau which has a free and open version, but does not have the ready capability to access data via a JSON API. Given team experience with visualization of large datasets, getting adequate performance also required development of a database for caching the resulting data.

## Preliminary Design Sprint and Review Tasks:

* Select and commit to Epic(s) and User Stories and establish Sprint Backlog (see below)
* Setup GitHub site and provide access to team
* Scale and install infrastructure components and tools
* Install Pentaho Community Edition components in infrastructure (<http://wiki.pentaho.com/display/COM/Latest+Stable+Builds>)
* Configure BI/visualization component
* Design a database to cache the event data for the Epic(s)
  + Identify/design the tables/fields needed from the source database
  + Identify/design the reference tables and values needed for coded fields
* Develop reference tables
* Develop service using Open FDA adverse event API to populate/synchronize/refresh database
* Integrate Pentaho with the database
* Design visualizations/UI for each epic and user story in backlog
* Document architecture and design
* Complete user testing
* Conduct Sprint Review with User SME
* Document installation instructions
* Complete supporting documentation needed for prototype submission
* Freeze GitHub content and make repository public
* Submit package to GSA

## Sprint Backlog

1. **EPIC**: As a Pharmaceutical Researcher I would like the ability to extract one or more common factors that could be contributing to an adverse drug event so that I can better assess the safety of certain Phase 4 drugs.
   1. **User Story:** As a Pharmaceutical Researcher I would like to determine if past adverse drug events can be correlated to a specific period of time within a year, or if they are seasonal correlations such as the high point of the allergy season.
   2. **User Story:** As a Pharmaceutical Researcher I would like to determine if past adverse drug events can be correlated to a specific age range of patients.
   3. **User Story:** As a Pharmaceutical Researcher I would like to determine if past adverse drug events can be correlated to the gender of patients.
   4. **User Story:** As a Pharmaceutical Researcher I would like to determine if past adverse drug events can be correlated to a specific weight range of patients.
   5. **User Story:** As a Pharmaceutical Researcher I would like to determine if past adverse drug events can be correlated to the country where the event occurred.
   6. **User Story:** As a Pharmaceutical Researcher I would like to determine if past adverse drug events can be correlated to the drug(s) patients are receiving.
   7. **User Story:** As a Pharmaceutical Researcher I would like to determine if past adverse drug events can be correlated to documented patient outcome(s).
   8. **User Story:** As a Pharmaceutical Researcher I would like to determine if past adverse drug events can be correlated to the reporter’s occupation.

## Dataset Mapping to API for Epic 1 User Stories

In preparation for prototype development, the Front End Web Designer (Data Scientist) developed an Open FDA API mapping for the data applicable to Epic 1. This were shared with the Pool 2 developers.

|  |  |
| --- | --- |
| **User Story** | **API Fields Used** |
| 1a | Safetyreportid, Receivedate (If the date the adverse event occurred or began is available, please include) |
| 1b | patient.patientonsetage, patient.patientonsetageunit |
| 1c | patient.patientsex |
| 1d | patient.patientweight |
| 1e | occurcountry |
| 1f | patient.drug.medicinalproduct, patient.drug.drugcumulativedosagenumb, patient.drug.drugcumulativedosageunit, patient.drug.drugdosageform, patient.drug.drugintervaldosagedefinition |
| 1g | patient.reaction.reactionoutcome |
| 1h | primarysource.qualification |

## Developing the Design Prototype

In the process of developing the design prototype, approximately 5 versions of the dashboard were created. In the first design prototype version, the adverse drug event report was shown as a table on the dashboard, and a set of filters was presented on the side for filtering adverse drug event records. Later, to see the trend of adverse drug events over time and to give more flexibility in filtering records, a table of adverse drug event counts over time was shown and more filters were added to create the second design prototype version. Also, more details of adverse drug events was included in the table to show what information was available.

In the third design prototype version, a demographic visualization dashboard was created in addition to the adverse event report dashboard based on usability recommendations from the Product Manager. This demographic visualization dashboard presented effective and intuitive visualizations of patient outcome, gender, age, weight, country, and drug usage. The same set of filters was presented in both dashboards for consistency, and to provide a more user friendly interface. The adverse drug event count table in the adverse event report dashboard was transformed into a trend line for similar usability reasons.

The fourth design prototype version added an adverse drug event count trend line by outcome visualization to compare the trend of adverse drug event counts across different outcomes. Labels were added to make it easier to see where the user story can be fulfilled using the dashboard.

In the final version of the design prototype, as recommended by our user SME, a new dashboard showing the percentage of adverse drug events containing listed drug(s) was created. In this new heat map dashboard, one can easily locate a single drug or a drug combination that has occurred frequently in adverse drug events since 1999, identifying potential drug to drug interactions. In preparing data to support this dashboard, drug and outcome data was merged in R using Primary ID as a key. The merged data was then flattened into records with a distinct Primary ID and concatenated drug name using an Excel Pivot table and functions. A count of adverse drug events containing listed drugs was later generated, also through Excel. Prepared data was then imported to Tableau and merge with existing data using Primary ID as the key to make sure all filters were available for the newly imported data. Other minor adjustments were also made to this dashboard to present a relevant and intuitive user interface that included column names, filter set, and the information displayed in the adverse drug event details.

# Design Review Meeting with User SME

After the initial design prototype was developed, the Product Manager and Front End Web Designer (Data Scientist) met again with a user SME to review that prototype. The meeting and related notes are documented below.

-----Original Appointment-----  
**From:** Robert Damashek   
**Sent:** Sunday, June 21, 2015 5:55 PM  
**To:** Robert Damashek; Chuck Rehberg ([chuck\_r@trigent.com](mailto:chuck_r@trigent.com)); Gail Chen; Rafael Diaz  
**Subject:** Review Open FDA Prototype  
**When:** Monday, June 22, 2015 4:00 PM-5:00 PM (UTC-05:00) Eastern Time (US & Canada).  
**Where:** Skype Meeting

## Notes:

We met with Chuck Rehberg again and presented an initial design prototype visualizing what our team was able to find in the dataset, building on the scenario we had previously discussed along with the dataset gaps identified in the data analysis and API mapping.

Chuck’s recommendation was to give the researcher the ability to explore the set of demographic combinations that co-occur with either a specific outcome or drug. These could be the initial filters supporting the scenario. It would then be useful to help the researcher explore all combinatorics, such as identifying the largest set of events for an outcome. He also recommended grouping numeric demographics like age and weight into a small set of range buckets to reduce the analytical and correlation complexity. We then could help the researcher explore what populations sharing the same demographics were most impacted by the drug. Gail indicated that we could do this by leveraging set operations in Tableau, using the parameters to establish the set. We also discussed diving deeper into the data by sub-setting the population demographics, and using a bubble chart to visualize each population category.

# Sprint Review

-----Original Appointment-----

From: Robert Damashek

Sent: Monday, July 06, 2015 4:42 PM

To: Robert Damashek; Chuck Rehberg (chuck\_r@trigent.com); Gail Chen; Rafael Diaz

Subject: Open FDA demos

When: Tuesday, July 07, 2015 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: Skype Meeting

## Notes:

We met with Chuck Rehberg as the user SME for the Sprint Review. We presented the final Development Prototype and he commented that the prototype is both intuitive and straightforward, and has useful functionality. He accepted the prototype.