Discovery: Preliminary Outcome/Capability Analysis for Open FDA Data

Analysts: Robert Damashek, Gail Chen

Sources: Open Web Search on Challenges, Risks and Disruptions between FDA and Regulated Industry; Discovery Interviews with FDA and Industry SMEs

Date: June 18, 2015

Articles Reviewed:

1. “Makers of Generic Drugs Challenge F.D.A. Plan for Updated Warnings”, New York Times, March 27, 2015. <http://www.nytimes.com/2015/03/28/science/makersofgenericdrugschallengefdaplanforupdatedwarnings.html?_r=0>
2. “Challenges and Opportunities for the Generic Drug Industry”, Remarks at the GPhA Annual Meeting as Delivered by Margaret A. Hamburg, M.D., FDA Commissioner, February 23, 2012. <http://www.fda.gov/NewsEvents/Speeches/ucm294978.htm>
3. “Regulation in the Medical Device Industry: FDA insider lays out the issues”, Metropolitan Corporate Counsel, March 19, 2015. <http://www.metrocorpcounsel.com/articles/31944/regulationmedicaldeviceindustryfdainsiderlaysoutissues>
4. “Device Tax Repeal, FDA’s Actions Affecting Industry Remain Top Issues”, Bloomberg Bureau of National Affairs, January 1, 2015. <http://www.fr.com/wp-content/uploads/2015/01/Bloomberg-BNA.Medical-Device-Law-Industry-Report.January21.2015.pdf>
5. “Project FDA Report: The Digital Future of Molecular Medicine: Rethinking FDA Regulation”, Manhattan Institute, May 2013. http://www.manhattan-institute.org/pdf/fda\_06.pdf

Interviewed:

1. Chuck Rehberg, Pharmaceutical Process and Data SME
2. Robert Zhenson, FDA Recall Regulatory Process SME

Candidate Capability: Regulatory and regulated entities need the ability to research, analyze and better understand potential causes of adverse events by looking at multiple factors present across a set of similar events.

Why Important: To detect issues in drugs on the market, plan changes in drug warning labelling, plan for product recalls for drugs involved in recurring events with serious outcomes, or plan for new drugs to avoid recurring adverse events.

Initial Product Backlog (epics and user stories):

1. EPIC: An FDA or Pharmaceutical Researcher wants the ability to explore if one or more common factors (any or all selected) are present across adverse events
   1. User Story: Research filters events based on date range
   2. User Story: Researcher filters events based on an age range selection
   3. User Story: Researcher filters events based on a gender selection(s)
   4. User Story: Researcher filters events based on the patient’s occupation(s)
   5. User Story: Researcher filters events based on the patient’s treatment(s)
   6. User Story: Researcher filters events based on the drug(s) patient is receiving
   7. User Story: Researcher filters events based on outcome(s)
   8. User Story: Research views the resulting population (count) of events over time
2. EPIC (stretch): An FDA or Pharmaceutical Researcher wants the ability to explore if drug-to-drug interactions may be playing a role in certain outcomes
   1. User Story: Researcher selects outcome(s)
   2. User Story: Researcher selects the minimum number of drugs that need to be found in combination in adverse events
   3. User Story: Researcher views the total population of events in which the selected outcomes and drug group size are found to be present
   4. User Story: Researcher filters events based on an age range selection
   5. User Story: Researcher filters events based on a gender selection(s)
   6. User Story: Researcher filters events based on the patient’s occupation(s)
   7. User Story: Researcher filters events based on the patient’s treatment(s)
   8. User Story: Researcher filters events based on outcome(s)
   9. User Story: Researcher filters events based on a date range selection
   10. User Story: Researcher selects a drug found in the event
   11. User Story: Researcher views all groups of drugs found to be present in combination with the selected drug in the filtered events
3. EPIC (alternate): A Physician wants the ability to explore if symptoms demonstrated by patient matches symptoms in adverse events
   1. User Story: Physician selects patient age
   2. User Story: Physician selects patient gender
   3. User Story: Physician selects patient treatment(s)
   4. User Story: Physician selects drugs patient is taking
   5. User Story: Physician views count of all adverse events with these in common
   6. User Story: Physician filters events based on the patient’s occupation(s)
   7. User Story: Physician filters events based on outcome(s)
   8. User Story: Physician filters events based on an age range selection
   9. User Story: Physician views count of all filtered events
   10. User Story: Physician drills down to view individual event details

Database Considerations:

* Adverse Event table contains 30,000 records, identified by Case Id, includes date occurred and reported
* Case Id is common Foreign Key in all related tables
* Demographics table contains patient data on patient age, gender, occupation (codes)
* Indications table contains data on patient treatments (large set of codes)
* Outcomes table contains data on patient outcomes (small set of codes)
* Drugs table contains data on drugs being taken by patient at the time of the event

Potential Sprint Tasks:

* Setup GitHub site and provide access to team
* 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
* Scale and install infrastructure components and tools
* Install Pentaho Community Edition components in infrastructure (<http://wiki.pentaho.com/display/COM/Latest+Stable+Builds>)
* Develop reference tables
* Develop service using Open FDA adverse event API to populate/synchronize/refresh database
* Integrate open source BI/visualization component
* Design visualizations/UI for each epic (Gail/Rafael)
* Document architecture and design (Rafael)
* Configure BI/visualization component (Gail)
* If Epic 2 is included, develop correlation model (Gail)
* Document installation instructions (Rafael)
* Complete unit and user (Chuck) testing
* Complete supporting documentation needed for prototype submission
* Freeze GitHub content
* Submit documentation to GSA