Response

To

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Federal Acquisition Service, Integrated Technology Service

National IT Commodity Program

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for

**Agile Delivery Services (ADS I)**

Submitted By



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**Agile Approach to Prototype Design and Development**

For the design and development of the prototype FDA Drug, Device, and Food datasets, we used a compressed Agile Sprint approach. We put together an Agile team for the roles of a Product Manager (Category 1), Visual Designer (Category 5), Interaction Designer/User Researcher/Usability Tester (Category 3), Frontend Web Developer (Category 6), Writer/Content Designer/Content Strategist (Category 4), Technical Architect (Category 2), Backend Web Developer (Category 7), and DevOps Engineer (Category 8). As with many Agile projects, and given that this was a short, limited prototype design and development effort, several roles were handled by a single person. For instance {*need some clarification here as to which roles were handled by a single person, i.e. “The Product Manager also took on the role of the Interaction Designer/User Researcher/Usability Tester: the Technical Architect also acted as the Backend Web Developer, DevOps Engineer” }*.

**Project Kick-off and Chartering.** A short project kick-off/chartering meeting was convened to establish the vision and goals of the prototype design and development effort and to determine the Agile approach to be used for the effort. The product manager led the entire team through the session. The vision and goals of the effort were expressed in terms of several User Epics. It was also decided that a generic user “John” would be used to represent the public users of the prototype system. The team also agreed on a Definition of Ready for the Sprints (Table 1) and a Definition of Done for the individual stories and the Sprints (Tables 2 and 3 respectively). We have found it important to identify and agree upon a Definition of Ready at the Sprint level to make sure that the entire Agile Development Team, including the Product Owner and other member Stakeholders, know what is needed and expected in order to start a Sprint with User Stories that can be worked on in a short Sprint.

Table 1. Sprint Definition of Ready

*Populate with what was decided upon at Friday night’s session, if available.*

Table 2. User Story Definition of Done

*Populate with what was decided upon at Friday night’s session, if available.*

Table 3. Sprint Definition of Done

*Populate with what was decided upon at Friday night’s session, if available.*

**Release Planning.** Following the kick-off/chartering meeting, a release planning meeting was conducted by the Agile Coach. The Epics were refined into smaller, discreet user stories. User stories are listed in Table 4. Note, that we used “John” to refer to a generic user that is a member of the general public that wishes to use the openFDA database. The team decided that the effort would be consist of 2 very short Sprints. It was also determined that several Technical Stories (also referred to as Technical Spikes) would be necessary to implement continuous integration with the Git Hub and the openFDA libraries and database. The Technical User Stories are summarized in Table 5.

Table 4. Prototype Epics and User Stories

|  |  |
| --- | --- |
| Epic | User Story |
| Reports Over Time | John wants to get a count of all adverse reports related to medical devices from 2000 to 2015 |
|  | John wants to get a count of all adverse reported related to medical devices from 2000 – 2015 that were submitted by consumers. |
|  | John wants to get a count of all adverse reports related to medical devices from 2000 – 2015 for “PACEMAKERS”. |
| Devices | John wants to get a count of all adverse reports related to medical devices. |
|  | John wants to get a count of adverse reports related to medical devices where the incidents occurred at home. |
|  | John wants to get a count of adverse reports related to medical devices where incidents occurred in hospitals. |
| Types of Events | John wants to get a count of adverse reports related to medical devices based on the type of incidents. |
|  | John wants to get a count of adverse reports related to medical devices based on the type of incidents that occurred in a hospital. |
|  | John wants to get a count of adverse reports related to medical devices based on the type of incidents caused by a hospital bed. |
| Drugs | John wants to get a count of all adverse drug event reports for drugs prescribed for “HYPERTENSION”, between the years 2004-2015, that resulted in death, a life threatening condition, hospitalization, disability, congenital anomaly, or other serious condition. |
|  | John wants to get a count of all adverse drug event reports, submitted by drug manufacturers, for drugs prescribed for “HYPERTENSION”, between the years 2004-2015, that resulted in death, a life threatening condition, hospitalization, disability, congenital anomaly, or other serious condition. |
|  | John wants to get a count of all adverse drug event reports, submitted by drug consumers, for drugs prescribed for “HYPERTENSION”, between the years 2004-2015, that resulted in death, a life threatening condition, hospitalization, disability, congenital anomaly, or other serious condition. |

Table 5. Technical Stories/Spikes.

*Need to add table with one line descriptions of Technical Stories that were identified Friday evening, if available*

**Sprint Planning and Backlog Story Grooming.** Following the Release Planning Session, the Agile Coach led the team through 2 combined Sprint Planning and Backlog Story Grooming sessions. The developers worked with our surrogate Product Owner on Backlog Grooming to ensure that each User Story was sufficiently defined and understood to allow the developers to begin work on them. As part of the Sprint Planning, points were assigned to each User Story and Technical Story to estimate the relative size and complexity of each story. {*if you remember, mention how points were assigned to the user stories by the team. It could have been something like “T-Shirt Sizing” in terms of Small, Medium, or Large; Fibonacci numbers; point poker, etc.}*. The user stories were then allocated to the 2 Sprints by the consensus. The developers worked with our surrogate user/Product Owner to determine Acceptance Criteria for each User Story.

**Sprinting.** Design and development was accomplished in 2 Sprints following the Sprint Planning and Backlog Grooming session. The team verified that the Sprint Readiness Criteria was satisfied before starting work on the Sprint, based on the user stories allocated to each Sprint. In Agile, design and development proceeded together, on a story basis. In keeping with Agile’s tenet of working software over comprehensive documentation, only those design artifacts needed by the developers and testers were developed. User stories were worked on individually. {please review the next couple of sentences to make sure that they make sense and are roughly what the team did. Please feel free to correct anything and add in any tools used} As developers completed coding on modules, they were integrated with the other software modules using continuous integration with GitHub. This allowed other members of the team to act as testers to perform User Functional Testing and Usability Testing.

As we were following a compressed Sprint approach for the short prototype effort, the Sprints ended when the User Stories were completed, in accordance with the User Story Definition of Done and our Sprint Definition of Done. Sprint 2 immediately followed Sprint 1. Upon completion of Sprint 2, some final integration testing was performed by the team to verify that the prototype had been properly integrated and built in the GitHub environment and integrated with the openFDA libraries.

During the Sprints, metrics were maintained on the progress of the work. The primary metrics were points completed versus points planned. A combined burn-down chart was maintained for both Sprints, shown in Figure 1.

Figure 1. Prototype Burn-Down Chart

*Need to add Burn-down Chart here, unless it is already being put into the spreadsheet. If you don’t have a burn-down chart, let me know*