**FDA Prototype Application URL:**

<http://medicaldevicesafety-aceinfo.elasticbeanstalk.com>

**FDA Prototype GitHub URL:**

<https://github.com/AceInfoSolutions/GSAADSBPA-FDAPrototype>

**AceInfo** is pleased to submit a working design/development prototype utilizing the related datasets and APIs for Adverse Events and Enforcement Reports of Medical Devices from <https://open.fda.gov>. The prototype shows “Medical Device Safety Trends” for the general public and for medical equipment procurement personnel. AceInfo believes that the prototype demonstrates our design practices and ability to consume, modify, remix, and display the FDA datasets in an Agile/DevOps based Continuous Integration and Continuous Delivery (CI/CD) process framework.

**Kick Off and Team Formation:** AceInfo held a RFQ review meeting to evaluate/formulate our capability and approach, and assigned the Product Manager and Delivery Manager for this effort. Together we reviewed the vision and expected outcomes and established a high performance, self-organizing delivery team, primarily using the following Labor Categories: Product Manager, Delivery Manager, Visual Designer, Business Analyst, Technical Architect, Frontend Web Developer, Backend Web Developer and DevOps Engineer. We selected three AceInfo employees familiar with FDA to function as customer users to accomplish the user-centric design and acceptance of the prototype, and engaged a medical professional as an external user/reviewer.

**Agile Delivery Process:** AceInfo established a Scrum based Agile delivery process for the prototype implementation and created a new project/scrum board in JIRA to cover story points and iteration planning for user stories. We implemented an Agile/DevOps based CI/CD process that meets the US Digital Services Playbook guidelines. The Scrum Team conducted multiple discovery sessions with customers and discussed the requirements, information and datasets/APIs available on open.fda.gov. We conducted multiple analysis and design sessions to understand the APIs, data sets, JSON meta-data and information/examples and identified personas, “General Public User” and “Medical Equipment Procurement Specialist”. We conducted user research through contextual, individual and system observation interviews and decomposed the features into six user stories with acceptance criteria. The user stories were prioritized by our customer to form the Minimum Viable Product (MVP). We estimated the story points for user stories in product backlog and assessed the relative complexity, interdependencies and IT assets like cloud platform and open source tools/technologies needed.

**Architecture and Design:** Our Visual Designer implemented a User Experience (UX) based, Human Centric design by working closely with the customers. We developed user interfaces and workflows and produced mockup screens by considering the usability and Section 508 requirements. We included user research, persona creation, information architecture, and usability testing to improve the efficiency of screen design per requirements. Our Technical Architect in collaboration with the rest of the Scrum Team designed the technical architecture and technology stack, comprised of Ruby on Rails, HTML5, CSS, Responsive design, Twitter Bootstrap, Chartkick, JavaScript and a CI/CD framework using JIRA, Git, Stash, Jenkins and Docker for containerization. FedRAMP certified Amazon Elastic Compute Cloud (EC2) PaaS was used to standup the development, test and production environments for the prototype.

**Implementation:** The DevOps Engineer configured the environments in AWS with required software tools and worked with the Developers of the Scrum Team as an integrated DevOps team to enable continuous integration and delivery of incremental releases daily. To achieve rapid deployment, we implemented continuous inspection and adaptation through acceptance test-driven development (ATDD) methodology, working with the stakeholders developing the most important features first. The Scrum Team worked in five time-boxed, 3-day sprints to deliver working code and quickly gain feedback from the Product Manager, Business Analysts, and customer/users to confirm acceptance. We conducted 30-minute, daily scrum stand-ups to socialize issues and resolve impediments. Ten iterative/incremental releases of the prototype were deployed into QA and production environment in AWS cloud as Docker images. We automated the build deployments and monitoring alerts in both test and production environments through DevOps methods.

Scrum artifacts including product and sprint backlogs, release and sprint burn-downs, velocity measurement charts, and retrospective summaries were maintained in JIRA for continual improvements and documentation of the delivery process. We demonstrated the application features being developed to the customer in an iterative manner during and at the end of sprints to receive continuous feedback. We prepared a responsive design with a style guide and tested the responsiveness of the site on mobile devices. Section 508 compliance was validated using WAVE.

Automated verification and validation of software releases was accomplished using Selenium based automated testing. We conducted automated load testing using JMeter and captured performance metrics. In addition, we used AWS provided continuous monitoring techniques and configured alerts for health/performance of the servers and benchmarked the numbers for response time, latency and throughput to resolve issues proactively.