J P Systems, Inc.
Client Case Studies

FDA Pilot Project for Reporting COVID-19 Immunization Adverse Events

This case study describes an FDA and VA joint pilot project for modernizing the VA Adverse Event Reporting System data transmission from manual faxed CDC VAERS forms to near real time automated transmission of COVID-19 vaccine adverse events to the FDA's new Biologics Effectiveness and Safety (BEST) system. The project enabled the automation of reporting from the field to the FDA. "The FDA Biologics Effectiveness and Safety (BEST) System was launched to expand and enhance the Center for Biologics Evaluation and Research's (CBER) access to new and better data sources, methods, tools, expertise and infrastructure to conduct surveillance and epidemiologic studies." (Source: FDA website)

Under the National Childhood Vaccine Injury Act (NCVIA), healthcare providers are required by law to report to the CDC VAERS system any adverse event listed in the VAERS Table of Reportable Events which occurs within the specified time period after vaccinations. These reports help CDC and FDA detect new or unusual adverse events that could indicate a problem with a vaccine. If it looks as though a vaccine might be causing a problem, FDA and CDC will investigate further and take action if needed.

VAERS (Vaccine Adverse Event Reporting System) is a CDC/FDA reporting system. Typically, they are reported to the CDC. Previously, the FDA obtained information from the CDC. The JPSys FDA Pilots are the first automated VAERS reports (translated to FHIR R4 Resources) that the FDA has been able to receive directly from a provider (i.e., VA).

Our first pilot modernized the processing of the CDC VAERS form for Adverse Event Reporting System (ADERS). This form is for immunization adverse event reporting to the CDC/FDA VAERS System. It accomplished three objectives:

1) Automated VA ADERS heavily manual, fax-based transmission of CDC Vaccine Adverse Event Report forms (VAERS) to electronic standards-based data exchange (using HL7 FHIR R4 Messaging) transmissions

2) Enabled the FDA to receive immunization Adverse Drug Events (ADEs) directly from the VA rather than indirectly through the CDC

3) Reported VA ADERS ADEs directly to the FDA's new CBER BEST system. The pilot went live, end-to-end, in January 2023 and was deemed a brilliant success for all three partners collaborating in the exchange: VA, the eHealth Exchange, and the FDA. The working system was delivered in less than six months, and all three entities were invited to present at the eHx Annual Summit in 2023.

Expansion of this project from reporting only COVID-19 immunization adverse events to all types of vaccine adverse events is underway, with expected completion with the FDA during Summer 2024. Both the VA and the FDA are interested in sending the same immunization adverse events reported to the FDA directly to the CDC VAERS system, mirroring our successful HL7 FHIR R4 Messaging pilot with the FDA. Our design is a low-code, no-code solution for our client.

The FDA BEST system is now assisting its legacy MedWatch system team in modernizing from fax-based to electronic messaging transmissions thanks to the success of our pilot. In developing this prototype, we've modernized the VA ADERS reporting system transmission and data exchanges from heavily manual fax-based VAERS form transmissions to RESTFul API, HL7 FHIR R4 Bundle data transmissions.

In FY24 Q4, the client will begin implementing a bi-directional query/response HL7 FHIR R4 Messaging pilot with the FDA. The FDA will initiate a request (query) for up to sixteen (16) clinical domains of information surrounding the COVID-19 Adverse event of concern previously reported by the VA to the FDA. The solution modernized the formerly manual phone call exchange between the agencies when the FDA wished to obtain additional clinical information from the VA for a reported case of interest. This represents true and valuable process modernization.

Clinical Quality Language (CQL) was designed to represent clinical knowledge that can be used for both the Clinical Decision Support (CDS) and Clinical Quality Measurement (CQM) domains. In FY24 Q4, we anticipate beginning the design and implementation of our prototype for executing an FDA CQL query against the VA's clinical longitudinal patient record surfacing myocarditis cases associated with a COVID-19 adverse event (supporting the FDA's Phenotype study). This is very well aligned with the FDA requirements as it automates the heavily manual analysis the process currently requires.

With this automated query solution, the FDA initiates a query with their desired CQL algorithm, drops the connection, and consumes the query result generated from the automated execution of the FDA CQL algorithm. This approach significantly reduces the impact on the VA processing system and data repository as these queries can be very resource intensive. The CQL query execution may be scheduled off-hours, with the results being returned to the FDA when they become available.

Currently, the FDA cannot find provider beta-test partners willing to execute their queries manually, let alone capable of automating the process. They hoped to email the query to the beta-test provider, manually execute the CQL queries against their clinical data repositories, then manually populate and send the result sets into a spreadsheet back to the FDA as a secure email attachment. The goal for the VA HIE is to automate system-to-system, high-quality data exchanges governed by an Implementation Guide. As a result, the project team presented a prototype to the FDA in May 2023 to automate this process in support of their Phenotype Study and BEST system. The FDA very enthusiastically received the design for this prototype.

To decrease development times and save money, the project repurposes proven, existing code (e.g., State Immunization Registry pre-fetch querying), reducing custom coding and eliminating unnecessary human intervention. Clinicians using our solutions no longer have to manually initiate queries to obtain community partner data and cut-and-paste the response into their current clinical workflow. Instead, information is automatically retrieved and seamlessly integrated into their clinical workflows.