Taking Acceleration to a New Level: How Prevail InfoWorks Enabled New FDA Format Submission First

In April of 2026, the FDA required sponsors to report serious and unexpected adverse reactions (SUSARs) using the updated E2B (R3) Electronic Format. The FDA pushed the compliance deadline back to October of 2026 since organizations were finding such difficulties including technical and content problems. Plus, the FDA's own testing tools stymied progress. Then, the agency invited a select few CROs to access a testing environment to find the resources to surmount the hurdles they created. On behalf of a sponsor recently acquired by Lilly, Prevail InfoWorks' Pharmacovigilance and Engineering teams worked with the FDA within our own systems to formulate test files to be submitted to their new testing environment. Prevail InfoWorks then became the first to provide our sponsors with success in filing in the new FDA Platform.

With the SUSARs submitted, the industry can take comfort that any study can report a SUSAR in compliance. Our Pharmacovigilance team enters the information into our Early Safety Signal Detection System which automatically submits the case to FDA Production. This is just the latest FDA test Prevail InfoWorks has passed with flying colors. You may be interested in hearing more case histories of safety firsts: cross-study correlations at the touch of a button, integrating historical, publication and competitor data in the live study safety databases, and building the body of work required for an entrance into the FDA's Single Phase 3 initiative.