JOURNAL OF CLINICAL RESEARCH BEST PRACTICES
Vol. 11, No. 8, August 2015 "Happy Trials to You"

On Site: FDA, Google Unite to Detect Search-Data Adverse Events

Seeking to identify previously unknown side effects in online search data, the FDA has turned to Google. It hopes to potentially gain insights into how to leverage the search engine leader's technologies and data to discover adverse events by looking at Internet search histories.

The proposed collaboration stemmed from a single meeting several months ago but only became known when the FDA posted a record of the event on its website that was recently cited by Bloomberg. That exploratory meeting is the latest in a series of regulatory steps to find new sources of information and processes to monitor the safety of drugs on the market.

For Google, there are analytic techniques used to uncover adverse-event-related searches — a capability discussed at the meeting by a senior researcher, Evgeniy Gabrilovich, who co-wrote a paper two years ago about using search query data to identify adverse drug reactions. The FDA's quest to work with Google follows an incremental plan to find new sources for information and processes to monitor safety of drugs on the market that has included collaborations with PatientsLikeMe, an online patient network. And Microsoft also has been working with the FDA for several years.

Both the FDA and Google, however, have chosen not to reveal further information. Chris Kelly, an FDA spokesman, told Bloomberg that the meeting was an introduction and a chance for the agency to consider how best to collaborate in identifying adverse event data. Neither Bloomberg nor the FDA would comment further.

The agency's primary tracking mechanism for identifying adverse events during the post-approval period is known as the FDA Adverse Event Reporting System, or FAERS. It is the cornerstone of the agency's post-approval drug safety surveillance, where reporting is mandatory for sponsors, but voluntary for healthcare professionals and patients.

Over the years, the number of adverse events reports has climbed steadily — an estimated one million reports were filed last year, according to the FDA. But the system, which has been around since the late 1990s, does not capture all adverse event reports because of underreporting, largely due to the mix of voluntary submissions by doctors and patients. They are made either directly through the FDA's MedWatch program or sent to the drug manufacturer. The reports made directly from biopharmaceutical companies, however, are a mandatory requirement.

In turning to Google and its search engine logs to improve adverse event reporting accuracy, the FDA is looking to social media to improve FAERS, as critics maintain the system is slow to detect safety concerns. Some maintain that FAERS data can't be used to weigh the safety of new drugs against older drugs' safety records. Others point to the FDA's approach to improve the accuracy of reporting on adverse events.

"Everyone is aware there is no perfect postmarketing drug surveillance system, but FAERS is the best we have and a report by the Institute for Safe Medication Practices (ISMP) says that the FDA needs to spend more money on [FAERS]," said Brian Overstreet, CEO of Adverse Events, a company that analyzes FAERS for payers, healthcare systems, and biopharmaceutical companies. "That Google-FDA meeting was an introduction but I don't know if anything will go beyond that. What's best for FAERS are three things: First, clean up the data collection process to make it easier to report and ensure data coming is clean and reliable. Second, incentivize or otherwise require more reporting from healthcare providers, as they provide the most reliable reports in FAERS. And finally, the FDA needs to speed the

release of FAERS data — there is currently a [seven-month-plus] delay on quarterly data releases."

For Dan Ulrey, founder and CEO of Midwest Clinical Support, a 20-year old independent site network, the FDA turning to Google to help spot adverse events is acceptable as long as there are no privacy violations.

"While I am old-fashioned in not being a big fan of social media, I can see the advantages for the FDA in looking to improving its adverse event reporting system as part of the post-approval process," said Ulrey. "My concern is making sure it complies with HIPAA (the federal Health Insurance Portability and Accountability Act) and keeps the information totally proprietary — that would be fine."

ISMP, a nonprofit group that tracks drug safety issues, reported that biopharmaceutical companies were submitting incomplete information in their adverse event concerns: Only 49.4% of the forms of serious side effects met basic standards for completeness, containing a patient's age, sex and date of the event. The FDA, however, claims the reports it collected met those basic standards in 85% of cases — a significant difference, as 97% of all adverse events are collected by the FAERS system. The research study also noted that thousands of case reports where adverse events was classified as non-serious indicated only common health problems such as a cold, the sniffles, or an injection that had been painful.

"Our conclusion: It seems clear that this drug safety monitoring system is in need of modernization," the ISMP report stated. "It suffers from a flood of low-quality reports from drug manufacturers and has not yet been updated for the changing environment in which drugs are marketed to health professionals and consumers."

The FDA's quest to work with Google also includes searching for new sources of information and processes to monitor the safety of drugs on the market. Because of its research collaboration with PatientsLikeMe, which has 110,000 adverse events reports on 1,000 different medications, the FDA now will be able to access and analyze more data as a supplement to FAERS.

The role of Gabrilovich, the senior Google researcher, stems from a previous employer, Yahoo, where in 2013 he co-authored a paper in the Journal of Medical Internet Research using 178 million Yahoo search queries to spot adverse events. A data mining specialist on identifying suspected drug interactions, he demonstrated through his research that search data can help find drug reactions "that have so far eluded discovery by the existing mechanisms."

— Ronald Rosenberg *This news story was featured in CenterWatch Weekly, one of several newsletters published by CenterWatch, the global source for clinical trials information, timely news, in-depth analysis, study grant and career opportunities, and the largest listing of industry-funded clinical trials on the Internet. For more information, visit http://www.centerwatch.com*.