IMMEDIATE RELEASE

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JOURNAL OF DRUG SAFETY PUBLISHES REPORT ON SYSTEM THAT ACCURATELY PREDICTS FUTURE DRUG LABELING CHANGES

Advera Health Analytics, Inc.: A Pharmacovigilance Signaling System Based On FDA Regulatory Action and Post-Marketing Adverse Event Reports.

SANTA ROSA, CALIFORNIA – March 7, 2016 – A study from Advera Health Analytics, Inc., *A Pharmacovigilance Signaling System based on FDA Regulatory Action and Post-Marketing Adverse Event Reports*, was published this week in Drug Safety. The study details a method to accurately predict future labeling changes the Food and Drug Administration (FDA) will make to prescription drugs.

Prescription drug labels contain safety warnings and information about potential adverse drug events that patients may encounter. The data contained in the labels are initially based on evidence gathered in clinical trials that are performed before the drug is approved for sale. Once the drug is approved and made available for sale, FDA monitors reports of new serious adverse events in the real world submitted to its FDA Adverse Event Reporting System (FAERS). If previously unreported serious adverse events occur frequently, FDA may change the drug's label to add more warnings to reflect these new adverse events. In the most serious cases, FDA may even remove the drug from the market.

Predicting FDA's future labeling changes is a key element to improving patient safety and reducing the billions of dollars in avoidable costs caused by adverse drug events. Many healthcare practitioners rely on FDA labeling changes to supplement their prescribing decisions. FDA, however, can often take years to make labeling changes after new adverse events emerge. Accelerating that timeline and being able to provide healthcare decision makers with advance notice of future potential labeling changes based on emerging trends in adverse events reporting is a crucial tool to fight unnecessary safety risk.

Today's published study highlights Advera Health Analytics' predictive algorithm called RxSignal. RxSignal is the only tool on the market that alerts users to emerging and/or previously unidentified side effect threats that may prompt a future FDA regulatory action. RxSignal takes the millions of potential adverse event concerns in Advera Health's curated FAERS data and isolates those that FDA is most likely to take action on based on a number of factors. As a result, RxSignal is shown in today's study to accurately predict 73% of future FDA labeling changes.

“When FDA makes a significant label change or takes a drug off the market it can have a negative effect on patients, health care systems and pharmaceutical companies,” explained Advera Health Analytics President Brian M. Overstreet. “Being able to calculate when a drug might trigger higher rates of unfavorable serious adverse events and patient outcomes is a powerful tool to predict regulatory actions, increase patient safety, and lower downstream medical costs.”

Keith Hoffman, Ph.D., Advera Health’s Vice President of Scientific Affairs, added, “Post-marketing adverse event data is a vital component of any comprehensive analysis of drug safety. Our mission is to help our clients to predict future FDA actions in order to increase patient safety. Today’s publication of our methodologies in Drug Safety is a major milestone in validating the RxSignal algorithm and related technology, both of which our clients have come to rely on over the past two years.”

To learn more about this report: http://link.springer.com/article/10.1007/s40264-016-0409-x

ABOUT ADVERA HEALTH ANALYTICS

Advera Health Analytics is a health informatics company that improves patient safety and reduces systemic healthcare costs through the comprehensive analysis of real world outcomes data. Advera Health Analytics makes these data accessible, actionable, and predictable. For more information visit adverahealth.com and connect with us on LinkedIn, Twitter and Facebook.