IMMEDIATE RELEASE

CONTACT:

Brenda Nashawaty
bnashawaty@adverahealth.com
617-688-3253

ADVERA HEALTH ANALYTICS LAUNCHES RXSIGNAL® 3.0, THE ONLY POST-MARKETING SIGNALING SYSTEM TO PREDICT FDA ACTION ON LABEL CHANGES

Key component of Adverse Events Explorer app shows a predictive rate over 70% for label changes with less than 30% false signal rate; focuses drug/adverse events pair universe down to 0.21% of potential signals

SANTA ROSA, CA…October 8, 2015 – Advera Health Analytics, Inc. announced today the launch of RxSignal® 3.0, the latest version of its proprietary tool which identifies serious adverse events (AEs) likely to be added to a drug's label. As part of the Adverse Events Explorer app, this release of RxSignal enhances the ability for managed care and pharma companies to proactively cut administrative and systemic costs, while simultaneously improving health outcomes.

RxSignal is a predictive algorithm that alerts users to emerging and/or previously unidentified side effect threats that may prompt a future FDA regulatory action. It is the only tool on the market that has such qualities. RxSignal capabilities are possible as a result of extensive data processing of FAERS data through Advera Health's RxFilter® technology.

With approximately 2,500 new drugs approved, about 1,500,000 new annual case reports being submitted to FDA, and millions of possible drug/AE pairs to track, the challenge is how to focus on emerging safety issues. For RxSignal 3.0 Advera Health studied 1,000+ FDA Safety Communications and associated label changes issued from 2008 to 2015.

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

Key Benefits of RxSignal 3.0:
- Produces accurate signals that lead to label changes involving important medical events while producing a low number of signals that do not lead to FDA label changes.
- Shows a predictive rate above 70% for label changes made for precisely the important safety issues Advera Health highlighted while producing less than a 30% false signal rate. These rates allow for significantly more actionable and reliable signal information that can alter the perceived safety profile of a drug as interpreted by health professionals and managed care organizations.

- Focuses the drug/AE pair universe down to 0.21% of potential signals. Of those remaining pairs, the updated RxSignal platform now demonstrates a high accuracy rate as well as a low false positive rate.

RxSignal is part of Advera Health's Adverse Events Explorer app that provides the highest quality, standardized and sourced data on post approval drug side effects from FAERS, as well as access to proprietary data via Freedom of Information Act (FOIA) requests. Managed care organizations, hospital systems, and pharmaceutical companies rely on Adverse Events Explorer to mitigate risk, reduce administration and systemic costs, and improve patient safety.

Keith Hoffman, Ph.D., Advera Health's Vice President of Scientific Affairs, added, "Post-marketing AE 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 save money and increase patient safety. The predictive power of RxSignal comes from the analytic power of our RxSuite of analytics combined with our unique ability to go through thousands of FDA alerts to determine which AE's FDA is most concerned with."

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, Facebook and Twitter.