New Study Published in JAMA Internal Medicine Points to Value of Real-World Evidence in Supporting Decision Making for Supplemental Indications

Aetion’s state-of-the-art analytics, transparency and audit trails instill confidence in research findings

NEW YORK (PRWEB) December 05, 2017 -- Aetion, a leader in delivering real-world evidence (RWE) and outcomes-based analytics solutions to life science companies and payers, today announced that its Aetion Evidence Platform™ was used as part of a study that was published in JAMA Internal Medicine that examined the use of real-world data analyses to inform regulatory decision making for supplemental indications.

In the study, Michael Fralick, M.D., from the Brigham and Women’s Hospital in Boston, and colleagues, used the Aetion Evidence Platform to conducted a cohort study in commercially-insured patients to determine whether healthcare databases could be used to confirm a supplemental indication for FDA-approved prescription drug telmisartan. The findings examined the results of a randomized clinical trial that used insurance claims data from a nationwide healthcare database to compare patient outcomes. The study replicated the results pointing to the conclusion that “in certain clinical scenarios, database studies may support supplemental effectiveness applications for already approved medications.”

“Last year’s 21st Century Cures Act, and the FDA Reauthorization Act of 2017, encourages use of RWE,” stated Sebastian Schneeweiss, M.D., Sc.D., co-founder and science lead at Aetion. “The findings of this study reinforce the value that longitudinal healthcare data can have in confirming results of randomized trials to determine supplemental indications. By using the Aetion Evidence Platform, researchers receive the state-of-the-art analytics, transparency and audit trails they need to instill confidence in decision making.”

Robert M. Califf, M.D., former commissioner of the FDA, provided a commentary to the study confirming the high technical quality of the Aetion-based work that “…offers a cogent summary of the care, insight, and expertise that can be applied to the daunting scientific problem of observational treatment comparisons.” Commenting on the future value of RWE in regulatory decision making, Califf goes on to state: “Such flexible use of real-world evidence could lead to the incorporation of many more indications into labeling and boost efforts to optimize the evidence base for health and health care.” He continues to say that, “Despite the need for more examples and robust efforts to guide the use of different methods for different circumstances, observational analyses have an important place in the continuum of clinical evidence.”

The Aetion Evidence Platform measures and analyzes the medical needs, effectiveness, safety and broader value of healthcare interventions using the best available science, allowing for improved patient outcomes and associated costs. Researchers utilize the platform to assess either local or cloud-based data to conduct these analyses.

About Aetion

Based in New York City, Aetion (pronounced eh-tee-ahn) is a leading healthcare technology company that delivers the real-world analytics and evidence needed for value-based care. With its patented rapid-cycle analytics™ technology, the Aetion Evidence Platform utilizes the everyday clinical and financial interactions of the healthcare system to unlock essential evidence about the effectiveness and value of medical treatments. Founded by Harvard Medical School faculty members and top biotech data technologists, Aetion enables payers and providers to collaborate with biopharmaceutical and medical device companies in real-time to develop...
therapeutic insights and make smart choices in patient care. The company is backed by Flare Capital Partners, Lakestar, Oxeon Ventures and other leading individual health technology investors. Learn more at www.aetion.com.

1 Michael Fralick, MD, et al, “Use of Health Care Databases to Support Supplemental Indications of Approved Medications,” JAMA Internal Medicine, November 20, 2017
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