FDA selects Aetion Evidence Platform® to advance regulatory science and innovation

The agency will use Aetion's scientifically validated software platform to develop a system of studies that enables rapid evidence generation for COVID-19 and future pandemics

NEW YORK, NY, October 21, 2021 — Today, Aetion announces that it is expanding its relationship with the U.S. Food and Drug Administration (FDA) to use real-world evidence (RWE) to study COVID-19 interventions and advance regulatory science and innovation. FDA and Aetion will use Aetion Evidence Platform® (AEP), validated software that enables efficient, transparent, and reliable RWE research, to develop a framework and system of studies for the rapid assessment of COVID-19 inpatient medical products.

This project is designed to demonstrate how using a platform-based approach furthers regulatory learnings on the use of RWE to inform decision-making. The work will also provide a scalable infrastructure for the rapid development and evaluation of COVID-19 therapies, which can be applied for future public health emergencies. This contract will support the agency's broader digital transformation efforts, which include its Technology and Data Modernization Action Plans as well as its recently announced Office of Digital Transformation.

agency in developing the rigorous scientific processes and RWE generation tools needed to quickly respond to future public health challenges."

The aim of this project is to further data familiarity and protocol standards to support real-world data (RWD) analyses among the broader research community. FDA will work with Aetion to define and prioritize key research questions; identify fit-for-purpose data sources; develop appropriate, validated, and applicable measurement algorithms to capture key exposures, subgroups, confounding variables, and outcomes; design template epidemiological studies applicable to a range of treatments; implement studies and generate transparent reporting using AEP; and build and disseminate knowledge via peer-reviewed publications and other avenues.

Aetion and FDA will build on learnings from the research collaboration announced in May 2020, in which FDA and Aetion explored the utility of RWD to advance the understanding of and response to COVID-19. Since launching the collaboration, FDA and Aetion have developed mechanisms to assess data fitness for use; identified methodological good practices on working with RWD for COVID-19; and built the foundation for rapid-cycle analytics to address critical and emergent public health questions.

About Aetion

Aetion is a health care analytics company that delivers real-world evidence for the manufacturers, purchasers, and regulators of medical treatments and technologies. The Aetion Evidence Platform® analyzes data from the real world to produce transparent, rapid, and scientifically validated answers on safety, effectiveness, and value. Founded by Harvard Medical School faculty members with decades of experience in epidemiology and health outcomes research, Aetion informs health care's most critical decisions—what works best, for whom, and when—to guide product development, commercialization, and payment innovation.

Aetion is based in New York City and backed by investors including New Enterprise Associates (NEA), Warburg Pincus, Flare Capital Partners, Greenspring Associates, Lakestar, B Capital, Foresite Capital, Town Hall Ventures, McKesson Ventures, Sanofi Ventures, EDBI, Johnson & Johnson Innovation—JJDC, Inc., UCB, Amgen Ventures, and Horizon Health Services, Inc. Learn more at aetion.com and follow us at @aetioninc.

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