

Leading Real-World Data and Analytics Organizations Form Industry Coalition to Advance Policies to Support Regulatory Use of Real-World Evidence

RWE Alliance Launched by Aetion, Flatiron Health, IQVIA, Syapse, and Tempus

Washington, D.C. (May 19, 2021) – Five real-world data (RWD) and analytics organizations today announced an industry coalition dedicated to advancing the use of real-world evidence (RWE) to support regulatory decisions. Founding members of the RWE Alliance are [Aetion](#), [Flatiron Health](#), [IQVIA](#), [Syapse](#), and [Tempus](#).

The [RWE Alliance](#) intends to engage with the Food and Drug Administration (FDA) and Congress to advocate for policies that advance the use of RWE in regulatory decision making and benefit patients. The RWE Alliance will collaborate with patient groups, biopharmaceutical and medical device companies and their trade associations, as well as other key stakeholders to support broader efforts around the use of RWE.

Through principled approaches, RWD can be transformed into RWE for regulatory decision making. RWD are health-related data derived from sources outside of clinical trials, such as electronic health records, administrative claims, product and disease registries, personal devices, wearables, and other health-related applications. RWE broadens the evidence available to the regulators, developers, and providers of treatments to facilitate the understanding of medical product safety and effectiveness. The use of RWE can benefit patients by speeding access to new treatment options and serving as a resource to better characterize treatment effects, including in underrepresented populations.

Both FDA and Congress have recognized the potential of RWE to increase knowledge about new treatments and vaccines to benefit public health. Congress included policies to advance the use of RWE in the 21st Century Cures Act, and FDA has taken steps to explore the use of RWE for regulatory decision making, including by issuing a framework for the Agency's RWE Program and by engaging in multiple RWE-focused research collaborations. The RWE Alliance intends to contribute to these and similar efforts, and to engage with FDA on its 2021 Guidance Agenda and 2022 user fee authorization.

“Events of the past year have made clear that evidence derived from RWD is critical to assessing the safety, effectiveness, and value of drugs, vaccines, devices, and diagnostics. The Alliance will help advance global RWE standards that reflect the utmost commitment to scientific credibility,” said Carolyn Magill, Chief Executive Officer at Aetion.

“The diversity of RWD and RWE use cases has expanded in breadth and depth in recent years,” said Michael Vasconcelles, MD, Chief Medical Officer at Flatiron Health. “Now is the

right time for those with the technical and scientific expertise in RWD and RWE to come together and work with other stakeholders to advance the policy frameworks, guidelines and standards needed to provide critical clinical insights and support rigorous, evidence-based decisions.”

“We applaud FDA’s ongoing leadership in forging the necessary public and private partnership to advance its use of RWE to monitor post-market safety and adverse events and to make regulatory decisions,” said Rob Kotchie, President, Real World Solutions, IQVIA. “As a member of the RWE Alliance, IQVIA is committed to furthering this FDA initiative and promoting use of RWE across all therapeutic areas with the ultimate goal of advancing patient outcomes and access to care.”

“RWD holds enormous potential for efficiently gained, broadened insights—for healthcare providers, life science companies, regulators, and policymakers,” said Ken Tarkoff, Chief Executive Officer at Syapse. “The Alliance will work to better represent diverse patient populations and voices to advance insights obtained through RWD.”

“We are excited about the launch of the RWE Alliance and look forward to furthering the objective of using RWE to benefit patients,” said Elaine Katrivanos, Senior Director, Regulatory Affairs, Tempus. “RWD can help with some of the biggest challenges in healthcare.”

For additional information visit www.rwealliance.org.

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