REAL-WORLD EVIDENCE ALLIANCE

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RWE Alliance Applauds FDA for Publishing RWE Submissions Data, Encourages FDA To Continue To Enhance Communication and Transparency Around the Use of RWE in Regulatory Decision Making

Washington, D.C. (August 20, 2024) – The RWE Alliance issued the following statement in response to the U.S. Food and Drug Administration's report on submissions to the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) that contain real-world evidence (RWE):

"The RWE Alliance commends the Agency for recently publishing its report on CDER and CBER submissions containing RWE, consistent with its PDUFA VII commitment. Since our founding in 2021, we have encouraged FDA to enhance communication about the Agency's uses of RWE in regulatory decision making. This is crucial for advancing best practices within the RWE ecosystem and for spreading awareness of the benefits that RWE ultimately delivers to patients. We applaud FDA for issuing the recent report, as it provides more transparency around some ways in which RWE is used to inform FDA's regulatory decision making.

"As FDA explained, its report captures only certain RWE submissions. It does not cover submissions containing RWE that provide supportive evidence or contextualize safety information. We encourage FDA to continue publishing information about RWE submissions and, in the future, expand the scope to provide even more information about how RWE is being used in submissions. We also urge the Agency to continue to publish narratives on successful submissions, including in its approval documents and through other means that help increase awareness. Greater transparency and information sharing about all uses of RWE will help reduce uncertainties for sponsors and equip the RWE ecosystem to continue to advance the use of RWE in clinical trial designs.

About RWE Alliance

The RWE Alliance a coalition of real-world data and analytics organizations with a common interest in harnessing the power of real-world evidence to inform regulatory decision making to improve the lives of patients.

https://rwealliance.org/

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