REAL-WORLD EVIDENCE ALLIANCE

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RWE Alliance Submits Comments on All Four Recent FDA RWE Guidances, Looks Toward Further Engagement to Advance Use of RWE to Benefit Patients

Washington, D.C. (March 9, 2022) – Today, the RWE Alliance submitted a substantial comment letter in response to the U.S. Food and Drug Administration's (FDA) recent draft guidance, "Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products."

The RWE Alliance commends the Agency for recently issuing four substantive draft guidances on key real-world data and evidence (RWD/E) topics as part of the Agency's RWE Program, consistent with the 21st Century Cures Act. This letter follows comments on FDA's draft guidances on RWD derived from electronic health records/medical claims and registries, as well as on the application of FDA's current data standards to submissions containing RWD.

The Alliance looks forward to engaging further with FDA as the Agency works to finalize these guidances and considers additional policy issues regarding the use of RWD/E in regulatory decision making.

About RWE Alliance

We are a coalition of real-world data (RWD) and analytics organizations with a common interest in harnessing the power of real-world evidence (RWE) to inform regulatory decision making to improve patients' lives. Our members have deep knowledge and experience working with healthcare data across disease areas and patient populations, and we aim to bring these collective insights to bear in support of RWE policies.

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