



FDA Announces New Center for Real-World Evidence Innovation

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On December 12, 2024, FDA's Center for Drug Evaluation and Research (CDER) announced a new CDER Center for Real-World Evidence Innovation (CCRI). The CCRI is intended to serve as the focal point to promote more efficient and consistent communications across CDER offices regarding real-world data (RWD) and real-world evidence (RWE).

Advancing the use of RWD/E has been a priority for the agency and for manufacturers. It has also been a focus of Congress, as reflected in the most recent Prescription Drug User Fee Act reauthorization. The establishment of the CCRI reflects the growing volume and complexity of data available to support drug development and the agency's efforts to keep pace with these evolving dynamics. Enhanced computing power, emerging technologies and advances in epidemiological and statistical methods are transforming the drug development and manufacturing paradigms. Against this backdrop, CCRI's goal is to expand, coordinate, and promote consistency across RWD/E-related activities in CDER. The new center will initially focus on (1) scientific review and policy to include guidance and policy development; (2) coordinated outreach and engagement (e.g., workshops, meetings with external interested parties); (3) support of regulatory science; and (4) knowledge management (e.g., centralized repository, internal training).

For additional information regarding the newly announced Center please see the [CCRI webpage](#).

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