

REAL-WORLD EVIDENCE: REGULATORY PRACTICE AND PROMISE

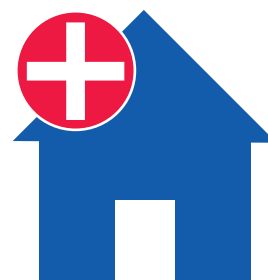
Real-world **data** are the data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. Real-world data can come from sources including:



electronic health records



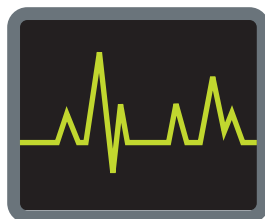
product/disease registries



patient-related
activities in out-patient
or in-home use settings



claims and billing



health-monitoring devices

Real-world **evidence** is the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of real-world data.

FDA has already been leveraging the power of real-world evidence for various purposes including regulatory decision-making, postmarket safety monitoring, and adverse event reporting.

The Center for Devices and Radiological Health (CDRH) regularly uses real-world evidence from sources including electronic health records and patient registries to support regulatory decision-making. CDRH reports over 50 regulatory decisions supported by real-world evidence.

The Sentinel Initiative, a decade-old endeavor to monitor the safety of medical products, relies on real-world data from electronic health records, disease registries, and insurance claims data.

CDRH's National Evaluation System for Health Technology is being built to more efficiently integrate real-world evidence into medical device decisions.

To build on these efforts to integrate real-world evidence into regulatory decisions, the FDA is going farther.

In 2017, the FDA released a guidance for industry, "Use of Real-world Evidence to Support Regulatory Decision-making for Medical Devices," to clarify for industry how real-world evidence is evaluated for medical devices based on their experience with previous reviews.

The Information Exchange and Data Transformation (INFORMED) program within the Oncology Center of Excellence seeks to expand organizational and technical infrastructure for big data analytics and examine modern approaches in evidence generation to support regulatory decisions.