

Real-World Evidence in Clinical Decision Making

Real-world evidence complements clinical trials by providing insights on outcomes relevant to everyday patient care¹

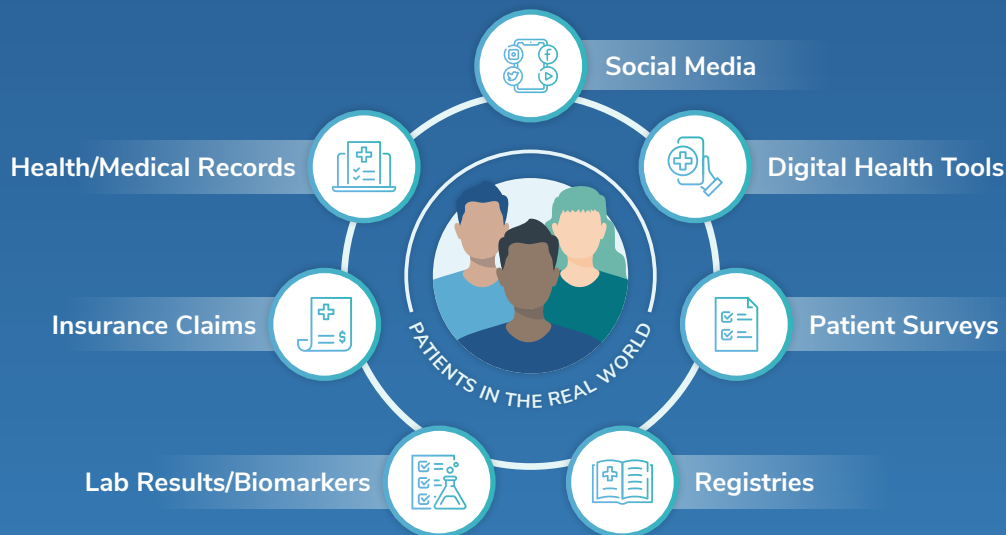
What Is Real-World Evidence?

Real-world evidence (RWE) is the clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of real-world data (RWD).²

What Are Real-World Data?

RWD are information relating to patient health status and/or the delivery of health care routinely collected from a variety of sources.²

What are examples of real-world data sources?^{3,4}



RWE should be interpreted within the larger clinical picture

RWD are not collected in a controlled research setting, so information may be incomplete, inconsistent, or influenced by factors that are difficult to measure.⁴ For example, insurance claims may contain coding errors, and patient surveys rely on self-report, which can be influenced by those who choose to respond.⁴

These limitations require RWE to be viewed as one piece of the overall picture of clinical treatment.⁵

How does RWE complement clinical trial data?^{1,5}



Broad, heterogeneous patient populations



Everyday clinical practice settings



Patient-centered, pragmatic insights



May support generalizability, help guide real-world decisions

1. Sherman RE, et al. N Engl J Med. 2016;375:2293-2297. DOI: 10.1056/NEJMs1609216. 2. US Food and Drug Administration. Real-world evidence. Accessed June 18, 2026. <https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence>. 3. US Food and Drug Administration. CDRH and real-world evidence. Accessed June 29, 2026. <https://www.fda.gov/medical-devices/science-and-research-medical-devices/cdrh-and-real-world-evidence>. 4. Liu F, Panagiotakos D. BMC Med Res Methodol. 2022;22:287. DOI: 10.1186/s12874-022-01768-6. 5. Swift B, et al. Clin Transl Sci. 2018;11:450-460. DOI: 10.1111/cts.12559.

RWE can answer questions from everyday clinical practice

How might a treatment perform in my patients?



Key insights from RWE¹⁻³

-  Clinical outcomes in diverse, real-world patient population
-  Treatment use patterns
-  Treatment effectiveness in routine clinical practice
-  Treatment effectiveness in clinically relevant subgroups

Examples¹⁻³

- ✓ Comparing hospitalization rates before and after treatment initiation
- ✓ Assessing treatment persistence and adherence over time
- ✓ Assessing incidence of relapse
- ✓ Examining outcomes among patients with comorbidities and other characteristics of interest



KEY TAKEAWAY

RWE complements clinical trial findings by providing data on how treatments perform in broader, real-world patient populations^{4,5}

How does a treatment compare with other available options in clinical practice?



Key insights from RWE^{2,5,6}

-  Comparative treatment effectiveness in real-world care
-  Differences in treatment utilization patterns
-  Comparative safety and tolerability
-  Differences in healthcare utilization and economic outcomes

Examples^{2,5,6}

- ✓ Comparing persistence and adherence between treatments
- ✓ Evaluating treatment-switching and discontinuation patterns
- ✓ Examining rates of adverse events in routine care
- ✓ Assessing healthcare utilization across treatment options
- ✓ Evaluating differences in healthcare costs



KEY TAKEAWAY

Comparative RWE complements clinical trials by providing evidence on how different treatment options perform in routine clinical practice⁵

What matters to patients when choosing a treatment and staying on it?



Key insights from RWE^{3,7-10}

-  Patient perspectives on treatment benefits and risks
-  Factors that influence treatment continuation
-  Treatment burden and tolerability in daily life
-  How patient experiences shape real-world treatment decisions

Examples^{3,7-10}

- ✓ Evaluating quality of life and daily functioning
- ✓ Assessing treatment satisfaction
- ✓ Understanding the impact of side effects on treatment decisions
- ✓ Assessing patient preferences for treatment attributes
- ✓ Exploring patient factors that may influence treatment persistence



KEY TAKEAWAY

Patient-centered RWE supports shared decision making by providing insights into patient experiences and treatment outcomes⁹

1. Cutler AJ, et al. *Adv Ther.* 2025;42(8):3691-3707. DOI: 10.1007/s12325-025-03211-w. 2. Cutler AJ, et al. *Psych Congress* 2025; Sep 17-21, 2025; San Diego, CA. 3. Swift B, et al. *Clin Transl Sci.* 2018;11:450-460. DOI: 10.1111/cts.12559. 4. Sherman RE, et al. *N Engl J Med.* 2016;375:2293-2297. DOI: 10.1056/NEJMs1609216. 5. Rudrapatna VA, Butte AJ. *J Clin Invest.* 2020;130(2):565-574. DOI: 10.1172/JCI129197. 6. Martin A, et al. *Adv Ther.* 2022;39(9):3933-3956. DOI: 10.1007/s12325-022-02232-z. 7. Doane MJ, et al. *Patient Pref Adherence.* 2020;14:2043-2054. DOI: 10.2147/PPA.S270020. 8. Doane MJ, et al. *BMC Psychiatry.* 2024;24:605. DOI: 10.1186/s12888-024-06034-1. 9. Anderson P, et al. *Curr Med Res Opin.* 2023; 39(12):1707-1715. DOI: 10.1080/03007995.2023.2279679. 10. Terpos E, et al. *Blood Cancer J.* 2021;11(2):40. DOI: 10.1038/s41408-021-00432-4.