

Real-World Evidence (RWE)

Randomized Controlled Trials

- Gold standard for efficacy
- Strict inclusion criteria
- Controlled environment
- Expensive & time-consuming
- Limited generalizability

Real-World Evidence

- Effectiveness in practice
- Diverse patient populations
- Natural clinical settings
- Lower cost, faster
- Confounding & bias challenges

Regulatory Acceptance

FDA increasingly accepts RWE for drug approvals, label expansions, and post-market surveillance. Key: rigorous study design and bias mitigation.