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# Randomized Control Trials Vs. Real-World Evidence

## RCTs and RWE are mutually complementary forms of evidence generation

Real-World Evidence (RWE) is a growing area of research not derived solely from the rigorously controlled standards of randomized controlled trials (RCT) but based on real-world patient data. RWE is gathered as an observational analysis of people in a less controlled environment and is focused on the efficacy and outcomes of therapies in a real-world setting.

### Randomized Control Trials

Focus: Efficacy of a Treatment

Definition: Artificial experiments designed to understand the efficacy of a treatment across a homogenous treatment group.

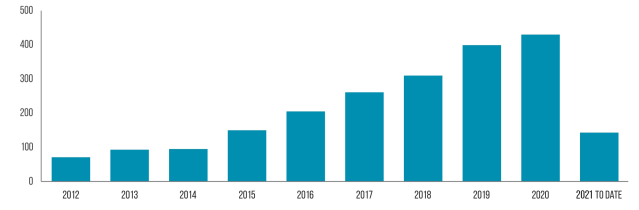
### Real-World Evidence

Focus: Effectiveness, safety, or costs of treatment

Definition: Observations of real-world populations in a heterogeneous group that reflects realistic scenarios, exposing the effectiveness of a treatment under various conditions

## Real World Studies

More than 2,000 Real World Studies Registered to Date




## KEY DIFFERENCES BETWEEN RCTs & RWE

| | RCTs | RWE |
|---|---|---|
| Purpose | Efficacy | Effectiveness |
| Setting | Experimental | Real-World |
| Follow-up | Designed | Actual Practice |
| Treatment | Fixed Pattern | Variable Pattern |
| Study Group | Homogenous | Heterogeneous |
| Patient Monitoring | Per Protocol | Changeable |

## ADVANTAGES OF RWE

*(compared with RCTs)*

- Less time and cost for evidence
- Safe research for high-risk groups
- Focus for special populations
- Detect low-frequency side effects
- Allows for comparison of treatment sequences
- More rapid data access and retrieval
- Foundational for AI

## LIMITATIONS OF RWE

*(compared with RCTs)*

- Doesn't allow accurate comparison with standard
- Selection bias is inherent
- Data quality may be lower
- More time for DQM
- Subject to multiple sources of bias
- Low internal validity

## Conclusion:

RWE can describe treatment efficacy in a "clinical practice" population. It can add insights on populations under-represented or excluded from pivotal clinical trials.

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