

Real-World Data (RWD)

Real-world data (RWD) refers to data related to patient health status and the delivery of healthcare that is collected outside the context of traditional randomized controlled trials (RCTs). It reflects routine clinical practice and is typically observational in nature.

Common Sources of RWD

- Electronic health records (EHRs)
- Health insurance claims and billing data
- Patient and disease registries
- Mobile devices and wearables
- Patient and provider surveys
- Pharmacy and laboratory records

Uses of Real-World Data

- Evaluating treatment effectiveness in real-world settings
- Monitoring safety and adverse events
- Supporting regulatory decisions (e.g., FDA, EMA)
- Informing clinical guidelines and health policy
- Designing pragmatic clinical trials

Limitations of RWD

- Potential for bias and confounding
- Missing or inconsistent data
- Limited control over data collection
- Challenges in data integration and standardization

RWD vs Randomized Controlled Trials (RCTs)

Feature	Real-World Data (RWD)	Randomized Controlled Trials (RCTs)
Setting	Routine clinical practice	Controlled experimental setting
Randomization	No	Yes
Generalizability	High	Often limited
Data quality	Variable	High
Bias control	Lower	Higher

Related Concept: Real-World Evidence (RWE)

Real-world evidence (RWE) is the clinical evidence regarding the use, benefits, or risks of a medical

product derived from analysis of RWD.

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