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The Synergy of Real-World Evidence and Clinical Trials

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Abstract

Randomized controlled trials (RCTs) have traditionally served as the cornerstone of clinical research, offering structured and highly regulated environments to assess the safety and efficacy of new medical products. While RCTs provide robust and scientifically controlled evidence, they often lack representation of diverse patient populations and real-world clinical behavior. In recent years, Real-World Evidence (RWE), derived from Real-World Data (RWD) such as electronic health records, patient registries, health insurance claims, and digital health platforms, has emerged as a valuable complement to traditional trial data.

The integration of RWE with RCT methodologies represents a notable evolution in medical research and drug development. This convergence aims not only to enhance scientific rigor but also to ensure that treatments proven effective in controlled settings remain meaningful, accessible, and truly beneficial in routine clinical practice. By examining current research and frameworks, this review highlights how RWE can inform trial feasibility, refine eligibility criteria, strengthen external validity, and offer insights into long-term safety and effectiveness that may not be fully captured during pre-approval studies.

A comparative assessment of RWE and RCT processes reveals complementary strengths: while RCTs excel in internal validity, RWE contributes broad applicability, patient diversity, and real-time feedback across large populations. The collaboration of these approaches is particularly valuable for rare diseases, accelerated approval pathways, post-marketing surveillance, and personalized medicine models. Emerging evidence suggests that thoughtfully integrating RWE into clinical development can support regulatory decision-making, optimize study designs, and shorten timelines without compromising scientific integrity. Ultimately, this blended model reflects a shift toward more holistic, patient-centered, and data-driven healthcare innovation. As adoption continues to grow, RWE paired with traditional clinical trials may reshape the future of evidence generation and support more impactful, equitable therapeutic advancements.

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