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The Intelligent Patient Journey: Artificial Intelligence as the Foundation of Precision Healthcare

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Short Communication

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Abstract

Clinical trials remain the foundation for evaluating the efficacy and safety of medicines, but their controlled conditions cannot fully represent the complexity of routine healthcare. Real-world evidence (RWE) provides a complementary second lens by examining how medicines perform across broader and more heterogeneous patient populations, treatment settings, and patterns of clinical use. Electronic health records, registries, claims data, patient-generated information, and other real-world data sources can contribute evidence about effectiveness, safety, adherence, treatment patterns, and outcomes that matter in everyday practice. However, RWE should complement rather than replace randomized clinical trials, because observational evidence can be affected by confounding, selection bias, missing data, and differences in data quality. Integrating trial evidence with carefully designed real-world studies can create a more continuous evidence framework for medicine evaluation and support treatment decisions that are both scientifically grounded and clinically relevant.

Keywords: Real-World Evidence; Clinical Trials; Real-World Data; Medicines; Treatment Decisions; Clinical Effectiveness; Patient-Centered Care; Drug Development

Introduction

Clinical trials are designed to answer carefully defined questions under controlled conditions. Randomization, protocol-driven treatment, and predefined outcomes provide strong protection against many sources of bias and remain essential for determining whether an intervention can work under specified circumstances. Yet patients encountered in everyday healthcare may differ substantially from trial populations in age, comorbidities, concomitant medicines, adherence, disease severity, socioeconomic circumstances, and access to care. Consequently, evidence generated in trials may require additional context before it can fully inform decisions across routine clinical practice [1].

Real-world evidence offers that additional perspective. By analyzing information generated during ordinary healthcare, researchers can evaluate how treatments perform across diverse populations and settings. Electronic health records, disease registries, insurance claims, pharmacy data, patient-reported outcomes, and other real-world sources can provide information on treatment utilization, comparative effectiveness, adverse events, persistence, adherence, and longer-term outcomes. When the research question, data source, study design, and analytic methods are appropriately aligned, these studies can extend knowledge beyond the boundaries of conventional trials.

The value of RWE is therefore best understood as complementary. A randomized clinical trial can establish an internally valid estimate of treatment effects, while a well-designed real-world study can help determine how those effects translate into heterogeneous clinical environments. This second lens can be especially useful for identifying

treatment patterns and outcomes among groups that may be underrepresented in trials. It can also contribute to post-authorization safety monitoring and to the assessment of effectiveness over longer periods of routine use [2].

At the same time, the availability of large datasets should not be confused with high-quality evidence. Real-world analyses can be influenced by confounding, selection effects, misclassification, missing information, changes in clinical practice, and differences between data systems. Strong study protocols, transparent reporting, appropriate statistical methods, validation of key variables, and careful interpretation are therefore necessary. Patient-centered approaches can further improve the relevance of RWE by ensuring that outcomes reflect questions and experiences that are meaningful to people receiving treatment.

Conclusion

Real-world evidence should not be viewed as an alternative to clinical trials, but as a second lens through which the performance and value of medicines can be understood. Linking randomized evidence with carefully generated evidence from routine care can provide a broader picture of effectiveness, safety, treatment patterns, and patient outcomes. The most useful evidence continuum will combine methodological rigor with clinical relevance, recognizing the strengths and limitations of each evidence source. As healthcare becomes increasingly data-rich, the goal should not simply be to collect more information, but to generate trustworthy evidence that helps clinicians and patients make better-informed treatment decisions.

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