DOI: 10.7860/JCDR/2025/76932.20744

Review Article

Pharmacology Section

Research beyond Randomised Controlled Trial: The Importance of Pragmatic Clinical Trials for Generating Real-world Evidence in Current Healthcare

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ABSTRACT

The potential of Real-world Evidence (RWE) to provide valuable insights from Real-world Data (RWD) has drawn a lot of attention recently. This shift focuses research from controlled conditions to real-world, everyday healthcare settings. The shortcomings of conventional Randomised Controlled Trials (RCTs) and Experimental Controlled Trials (ECTs) have led to the emergence of Pragmatic Clinical Trials (PCTs), which emphasise real-world, everyday healthcare settings. The various studies argues that PCTs can bridge the gap between efficacy and practical application in clinical research by incorporating diverse patient groups, adaptable procedures and outcome measures relevant to daily clinical practice. Therefore, this current study highlights the potential of PCTs to connect RCTs and clinical practice by examining the concept of RWE and the tests' distinguishing features.

Keywords: Clinical practice, Explanatory trial, Real-world data

INTRODUCTION

The healthcare sector has recently adopted an approach that prioritises RWE as a crucial element of clinical decision-making and regulatory evaluations. RWD, which includes information compiled from several sources about patient health and healthcare delivery, is essential for this purpose [1]. Clinical data, including Electronic Health Records (EHR), product and disease registries, insurance information and patient claims, is vital for validating clinical trial findings and addressing knowledge gaps in real-world medical situations. The insights gleaned from these studies can benefit various healthcare stakeholders [2]. While provider and payer organisations may use the data to better understand the cost, safety and efficacy of pharmaceuticals in the real world, healthcare providers can utilise it in conjunction with RCTs to assist in guiding routine patient treatment choices [3].

Although RWD can address design flaws in traditional RCTs, which are considered the gold standard for demonstrating safety and efficacy in controlled settings, it often fails to accurately represent therapies in diverse, real-world patient populations [4]. Through the evaluation of therapies in real-world settings, PCTs have become an invaluable link, providing vital insights. RWE enhances safety surveillance, effectiveness, outcomes research and disease progression but faces constraints in India, such as maintaining scientific rigor, managing large irregular data sets and ensuring data quality, which can potentially reduce its effectiveness [5]. Therefore, this article covers the importance, purposes and expanding roles of RWE and PCTs in healthcare.

Global Scenario: Real-world Evidence Study Design and Regulatory Bodies

Research designs for RWE studies can be categorised based on the type of data employed, the duration of the study, the exposure assignment and the framework defined by scientific societies, regulatory bodies, or initiatives [6]. Since there is no standardised system for classifying RWE study designs, various perspectives are briefly covered below. The availability of large datasets in healthcare has led to advanced techniques for gathering and evaluating RWE, influencing healthcare decisions and enabling more informed choices based on average patient outcomes. Regulatory agencies like the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) increasingly consider RWE for post-marketing surveillance, label extensions and medication approvals [7]. For instance, the FDA created the RWE program framework to evaluate RWE applications in support of new intended labelling claims-approval of new indications of already marketed or approved medicines. The EMA is embracing RWD research and advocating for a global, learning healthcare system that regularly incorporates new patient data, driven by the growing emphasis on patient-centered care and the need to understand medicines across various groups [8]. The EMA lacks a structured RWE framework comparable to that of the U.S. FDA. In 2018, it published a regulatory perspective on RWE, covering primary, secondary and post-approval safety and efficacy studies. In September 2020, it released a draft guideline on registry-based studies, providing manufacturers with methodological suggestions for patient registries [9]. "Optimising the Use of Real-World Evidence to Inform Decision Making," a 2019 publication from Health Canada, places more emphasis on the quality of RWD and evidence than on research methods [10].

The GetReal Institute is a European initiative aimed at improving healthcare decision-making through real-time engineering. Its RWE navigator assists users, such as patients, patient groups, regulators and health technology specialists, in understanding RWE principles, challenges and research organisation. The institute categorises RWE designs and techniques into primary data collection, secondary data utilisation and hybrid designs, promoting sustainable development and best practices [11].

However, there is no Indian framework outlining various RWE study designs. In India, the Indian Society of Clinical Research (ISCR) has launched the RWE council to promote awareness and utilisation of RWE among clinical research professionals, organisations, ethics committees and investigators in India, aiming to enhance RWE implementation across the country. Key goals include engaging with legislators—specifically those in charge of the Indian Council of Medical Research (ICMR), senior bureaucrats connected to the Health Ministry and the Central Drugs Standard Control Organisation (CDSCO)—to discuss a policy framework for RWE research, offering

professional training programs to equip stakeholders with essential skills and building a network of qualified experts. The council also aims to generate evidence for RWE in India in the form of case studies and position papers. Additionally, the council aims to provide tangible evidence of successful RWE implementation, supporting the integration of RWE into clinical research practices and improving patient outcomes across India [11].

Over 70% of Indians reside in rural areas, generating demand for healthcare providers such as government and private hospitals, health insurers and community health clinics. However, obstacles such as electronic medical records, data quality, insurance and claims data and a lack of medical compliance may hinder the implementation process [12]. To fully leverage RWD and RWE in India, coordinated efforts are being made, including the integration of digital healthcare technologies and the creation of patient registries [11]. India is now collaborating with other countries to utilise Remote Working and Electronic Health (RWD/E) to improve healthcare. Programs like the Ayushman Bharat Yojana and the National Digital Health Mission coordinate RWD sources. Progress requires time, patience and dedication to collect data and standardise instruments [13]. The National Digital Health Mission (NDHM), or Ayushman Bharat Digital Mission (ABDM), is enhancing healthcare outcomes by generating real-time data and RWE through a unified health data platform, EHRs and health information exchanges. This supports chronic disease management, promotes innovation and improves healthcare outcomes [12,13].

The perception of Indian clinicians toward RWE is unclear, as they are occupied with their routine practice and have little time or inclination for clinical research. Therefore, it is unlikely that they possess comprehensive knowledge of RWE concepts and values. For instance, structured RWE research can benefit physicians by eliminating the need for further planning or statistical analysis, using patient data from their practice. However, concerns regarding data collection and documentation remain unclear. Understanding effective treatments for specific patients can improve patient care and strengthen evidence for future practices [12,14]. Additionally, sponsors prioritise financial support and reduce monitoring of RWE studies, potentially impacting data quality and relevance to clinical practice. Low interest and dedication from clinicians contribute to the limited number of RWE studies in India [13].

Pragmatic Clinical Trials (PCTs)

Pragmatic studies, also known as low-interventional studies, aim to measure the relative effectiveness of treatment approaches within actual or real-world clinical settings [15]. These studies exhibit the tangible benefits of a treatment in everyday practice while maintaining the rigor of RCTs [16]. The concept of pragmatism in clinical trials was first introduced by Schwartz and Lellouch in 1967, who classified randomised studies into two types: “explanatory” and “pragmatic.” Explanatory Clinical Trials (ECTs) focus on comparing treatments under highly controlled, uniform conditions to understand their biological effects and efficacy. In contrast, PCTs aim to evaluate the effectiveness of treatments in routine clinical settings, making the findings more applicable to real-world practice [17]. Since the introduction of PCTs, various researchers have developed criteria to further distinguish them from ECTs, emphasising their unique role in addressing practical, patient-centred outcomes within everyday healthcare environments. While PCTs evaluate whether the intervention is effective in real-world situations, ECTs ascertain whether the intervention is effective in controlled situations [17,18].

The PRagmatic Explanatory Continuum Indicator Summary (PRECIS) tool, introduced in 2009, was developed to help researchers design trials that clearly align with their goals by distinguishing between explanatory and pragmatic approaches [4]. In 2015, an updated version, PRECIS-2, was released with more flexibility, allowing investigators to assess trial designs across an explanatory/pragmatic continuum in nine distinct domains: eligibility criteria, recruitment, setting, organisation, delivery flexibility, adherence flexibility, data collection, primary outcome and primary analysis. This tool has since guided the design of hundreds of RCTs, helping researchers choose the type of trial that best suits their objectives [17,18]. However, certain features of PRECIS-2, particularly when applied to provider-focused implementation studies rather than patient-centered intervention trials, could benefit from further clarification. Recognising this, Norton WE et al., expanded the tool by creating the PRECIS-2-Provider Strategies (PRECIS-2-PS) instrument, tailored specifically for trials evaluating strategies focused on healthcare providers rather than patients. This adaptation allows for more nuanced trial design in studies aimed at implementing changes within healthcare provider practices [19].

Pragmatic trials assess randomised patient groups with similar characteristics to the target population in real-world healthcare settings, considering factors such as co-medications, patient compliance and placebo effects. These trials aim to improve the generalisability of results to a larger patient group, making them useful for decision-makers and health technology assessment organisations involved in payment and policy choices. The findings are relevant to everyday practice and must align with standard clinical procedures [15,17]. PCTs are a method that promotes informed healthcare choices by considering the complexity of routine clinical treatment and actual patient experiences. They focus on evaluating the effectiveness of treatments in real-life scenarios, offering more broadly applicable data than traditional RCTs, which aim to reduce variables and provide the best feasible environment for efficacy assessment [4,20].

PCTs are recommended for RWE delivery due to their ability to provide evidence quickly and effectively, mimicking accepted therapeutic procedures by combining the scientific rigor of RCTs with the practical applicability of observational studies, thus addressing real-world stakeholder issues [1]. The PCTs, also known as embedded PCTs (ePCTs), are clinical trials that randomly assign patients and evaluate the efficacy of interventions in various clinical contexts. The increasing relevance and accessibility of RWE have led to a worldwide interest in PCTs. Over 600 trials conducted between 1977 and 2017 had “pragmatic” titles, with over half concentrated between 2014 and 2017 [21].

PCTs are relevant in real-world clinical practice due to their broad patient criteria, flexible protocols and focus on outcome measures such as quality of life, hospitalisation rates and treatment adherence. They allow for a diverse population, including patients with co-morbidities and varying ages and align with practice-specific treatments. Unlike traditional trials that rely on surrogate endpoints, PCTs focus on outcome measures that matter in routine care, such as quality of life, hospitalisation rates and treatment adherence. These factors make PCTs valuable for understanding the impact, efficacy, adherence and long-term safety of real-world interventions. They are particularly useful for comparing therapeutic options for complex chronic conditions like diabetes, cardiovascular disease and mental health disorders, providing insights that are relevant to healthcare providers, policymakers and patients.

Benefits and Advantages of using RWE and PCTs

The integration of RWE and PCTs enhances patient outcomes and aids in medical decision-making by providing practical insights into treatment efficacy in typical clinical situations, supplementing data from RCTs [22]. This evidence is crucial as it provides data on the effectiveness and safety of therapies for various patient populations, including those underrepresented in RCTs. Additionally, it can help healthcare practitioners identify new trends and customise treatments to improve patient outcomes by gaining a deeper understanding of real-world treatment results [22,23].

RWE is increasingly important for regulatory agencies in post-marketing surveillance and the licensing of medicines and devices. It can expedite

the approval process for medicines by supplementing RCT data with real-world insights, addressing gaps in effectiveness and safety data not recorded in controlled trial settings. RWE is also essential for post-market surveillance, tracking long-term safety and detecting side-effects following the introduction of therapies to larger populations [24].

Similarly, by merging the practical applicability of observational studies with the scientific rigor of RCTs, PCTs make a substantial contribution to the healthcare environment. Platform Trials (PCTs) are a method used to assess multiple therapies simultaneously within a single framework, providing a comprehensive understanding of their effectiveness in real-life situations. These trials are adaptable, allowing for the addition or removal of new therapies as they become available. PCTs are less expensive and demanding than traditional RCTs. This method ensures study validity and reliability by standardising patient selection and integrating PCTs into clinical settings, demonstrating the success of various therapies in everyday care and providing valuable information on affordable healthcare alternatives [16,19,22].

By incorporating larger and more diverse patient groups, the combination of RWE and PCTs enhances the generalisability of clinical research, increasing its relevance for routine medical practice. Both approaches emphasise patient wellbeing and relevance in healthcare, focusing on patient-centered outcomes such as quality of life and long-term safety. These approaches promote a patient-centric perspective, providing a comprehensive understanding of therapy effects and enabling policymakers and healthcare professionals to make data-driven decisions that directly benefit patients [25].

RWE and PCTs are revolutionising clinical research by incorporating real-world perspectives into trials. Their combined influence on patient care, regulatory procedures and resource distribution emphasises the importance of including real-world viewpoints in clinical trials. By strengthening the evidence foundation, encouraging results that promote inclusivity, effectiveness and efficiency and bridging the gap between research and practice, RWE and PCTs are transforming healthcare [26]. [Table/Fig-1] shows comparison of key features of RCTs, PCTs and RWE.

Applications and Challenges of Implementation of RWE and PCTs

RWE and PCTs have significant potential to enhance healthcare, particularly in regulatory decision-making, comparative effectiveness research, post-marketing surveillance and chronic illness management. Both are crucial in treating chronic diseases like diabetes, hypertension and cardiovascular disease, allowing doctors and researchers to assess therapy efficacy across diverse patient profiles and co-morbidities, which are often overlooked in conventional RCTs [1,17,27].

RWD is essential in post-marketing monitoring, helping regulators and medical practitioners monitor the long-term safety of medications once they become widely accessible. RWE reveals uncommon side-effects and consequences that may go undetected in clinical trials but can affect specific patient populations. By using RWD, regulatory agencies can make more informed decisions about a drug's safety profile. In this context, PCTs play a crucial role in comparative effectiveness research, evaluating various therapies in real-world settings to determine the best course of action for specific patient groups. This direct comparison of interventions improves treatment plans and outcomes, enhancing patient experiences as well as healthcare professionals' experiences [20,28].

Additionally, RWE is increasingly being utilised by regulatory bodies like the FDA and EMA for evaluating novel indications for authorised medications. This ensures that regulatory decisions are based on data reflecting routine clinical practice, allowing for a more comprehensive assessment of treatment options. RWE and PCTs are transforming healthcare by facilitating data-driven choices, ultimately improving patient care [27,29].

While RWE and PCTs have potential applications, challenges such as disparities in healthcare systems, particularly in EHRs, impact their reliability. Data quality and standardisation remain major concerns, as variability in data collection, processing and integration can skew real-world insights and restrict RWE's ability to generate consistently high-quality results [2,6].

The issue of preserving patient privacy and upholding ethical norms is a significant challenge, as strict compliance with privacy regulations such as Health Insurance Portability and Accountability Act (HIPAA) in the U.S. and ethical standards is necessary for RWD collection and use. Researchers and institutions often grapple with ethical issues in this regard [28].

Integrating personal care technology into healthcare systems presents logistical challenges due to potential workflow modifications that may not align with clinical procedures. This necessitates careful planning and adaptation across diverse healthcare contexts, which can be time-consuming and resource-intensive [19]. Finally, to enhance the reliability of PCTs, it is crucial to address interpretability and bias concerns. PCTs are more susceptible to real-world biases than RCTs and thus, precise procedures are needed to minimise bias and ensure accurate medical judgments. This will help maximise the influence of RWE and PCTs on patient care and regulatory decision-making [4,19].

Future Directions

While healthcare systems, regulatory agencies and academics are increasingly utilising RWD analysis and PCTs in addition to standard RCTs, emerging technologies like artificial intelligence, machine learning and data analytics are expected to enhance RWE gathering and analysis. These advancements will enable the recording of real-world patient outcomes with unprecedented relevance and detail. These technologies will improve the quality of RWE by managing medical data complexity and offering insights more aligned with routine clinical practice [16,19,30].

Clinical research is expected to adopt a more integrated approach, combining the practicality of RCTs with the rigor of RCTs. This

Parameters	Randomised Controlled Trial (RCT)	Pragmatic Clinical Trial (PCT)	Real-world Evidence (RWE)
Study sites	Limited, controlled and standardised	Multiple, diverse, real-world settings	Broad – hospitals, clinics and pharmacies
Settings	Highly controlled, experimental environments	Routine healthcare settings	Every day and usual clinical setting
Inclusion criteria	Strict criteria to exclude high-risk or poorly adherent participants	Broad criteria to include various participants	Capturing all eligible participants
Intervention	Thorough delivery and monitoring intervention	Flexible delivery and monitoring of intervention	Observed as part of usual care of treatment
Comparator	Generally placebo control	Routine clinical treatment, mostly not placebo control	Existing treatments or practices
Sample size	Comparatively small	Usually large and diverse population	Very large, involving diverse population
Relevance to practice	Low relevance to practice, mostly focused on internal validity and efficacy	High relevance to practice, aimed at understanding effectiveness in real-world settings	Very high, directly associated with clinical and public health decisions
Follow-up period	Relative short period	Long-term follow-up	Variable, usually depend

[Table/Fig-1]: Comparison among the key features of RCTs, PCTs and RWE.

shift towards a patient-centred healthcare paradigm benefits both patients and providers by enabling evidence-based decisions that prioritise safety, effectiveness and relevance. As healthcare shifts towards value-based care, RWE and PCTs will become increasingly important in creating efficient, accessible and customised medical interventions for diverse patient demographics [25,31].

RWD analysis can significantly boost product development success in life sciences organisations, but it requires high-quality data and overcoming interoperability and access hurdles. EHRs are crucial for assessing treatment effectiveness and patient health impacts. EHR data offers deeper insights into patient health journeys, while claims data is useful for accuracy. Healthcare organisations are increasing EHR accessibility for research while maintaining patient privacy regulations. Global health research networks are utilising artificial intelligence and advanced analytics to facilitate real-time sharing of RWD in clinical centres, promoting a more effective and equitable healthcare environment. They are also developing their own data analytics frameworks, prioritising patient privacy and informed consent while ensuring stakeholder access to RWD [7,26].

CONCLUSION(S)

This review emphasises the significance of RWE and PCTs in clinical trials and research, highlighting their potential to improve medication safety and health. PCTs can bridge the gap between real-world drug application and controlled settings, overcoming obstacles that hinder RWE adoption in India. These technologies will play a revolutionary role in promoting clinical research and enhancing patient outcomes.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Nov 22, 2024
- Manual Googling: Jan 13, 2025
- iThenticate Software: Jan 15, 2025 (10%)

ETYMOLOGY: Author Origin

EMENDATIONS: 6

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was informed consent obtained from the subjects involved in the study? NA
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Nov 21, 2024**
Date of Peer Review: **Dec 14, 2024**
Date of Acceptance: **Jan 17, 2025**
Date of Publishing: **Mar 01, 2025**