REVIEW ARTICLE

Evaluating India's Position in Pragmatic Clinical Trial for Public Healthcare: A Key to Real World Healthcare Solutions

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ABSTRACT

Pragmatic Clinical Trials (PCTs) are valuable tools for evaluating interventions in real-world settings, providing insights for clinical practice. Unlike traditional randomized controlled trial (RCTs), PCTs generate real-world evidence for better decision-making. With 615 reported globally between 1967 and 2017, a 58% increase from 2013 to 2017, India has only one registered PCT, indicating a gap in its adoption. This review examines national clinical trial registries, PubMed database for PCTs till 2024, comparing data across different nations. The study reveals a significant shortage of PCTs in India and a lack of awareness of frameworks like Pragmatic Explanatory Continuum Indicator Summary 2. India faces challenges in implementing PCTs due to low awareness, inadequate infrastructure, and logistical hurdles. However, with regulatory reforms, international collaboration, and infrastructure improvements, India can become a key player in advancing PCTs. Increased awareness and researcher training will contribute to better healthcare outcomes both domestically and globally.

Keywords: PRECIS-2, Pragmatic clinical trial, India, Real world evidence

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INTRODUCTION

Pragmatic clinical trials (PCTs) have gained significant attention and increasing exponentially in healthcare and pharmacy practice research due to their emphasis on real-world applicability and scalability across diverse practice environments.[1] During the period from 1967 to 2017 (a span of 40 years), a total of 615 Pragmatic Randomized Controlled Trials (PRCTs) were reported. Of these, 261 were reported between 1977 and 2013, and there was a 58% increase in the next four years, with 334 PRCTs reported.[2] Unlike traditional randomized clinical trials (RCTs), which focus on tightly controlled settings, PCTs are designed to evaluate how interventions work in everyday environments with diverse populations, making their findings more relevant for clinical decision-making.[3]

The distinction between "explanatory" and "pragmatic" trials was first introduced by Daniel Schwartz and Joseph Lellouch in 1967. Explanatory trials, as they defined, focus on determining whether a difference exists between two treatments under highly controlled conditions, while pragmatic trials aim to generate results that are directly applicable to routine clinical practice. Explanatory trials often lack generalizability due to their rigid controls, whereas PCTs, conducted in real-world healthcare settings, better reflect actual clinical scenarios.[4] In clinical trials, the primary goal is to assess the safety and efficacy of an intervention. However, it's crucial to distinguish between "efficacy" and "effectiveness": efficacy refers to how well an intervention works under ideal, controlled conditions, while effectiveness relates to its performance in real-world circumstances. Traditional clinical trials often optimize for efficacy by controlling numerous variables and carefully training staff. However, interventions that perform well under these ideal conditions may not be as effective in real-world settings due to factors such as patient non-compliance or the challenges of implementing the intervention in everyday practice.[1,5]

This shift toward pragmatic research reflects the complexities of real-world medical practice, where highly structured protocols may not be feasible without substantial resources. PCTs offer greater flexibility, often relying on data that clinicians naturally collect during routine patient care rather than following strict, protocol-driven data collection processes. This "real-world data," often sourced from electronic health records, may be less structured but can still yield valuable insights when analyzed with advanced techniques like machine learning and artificial intelligence, even amid the inherent variability.[6]

To aid researchers in designing and evaluating clinical trials along the continuum between explanatory and pragmatic approaches PRECIS (Pragmatic-Explanatory Continuum Indicator Summary) instrument was developed. In practice, it can be challenging to strictly categorize trials as either explanatory or pragmatic, as most trials possess elements of both. Initially, Gartlehner et al**.** proposed a framework with seven dimensions to assess a trial's pragmatic or explanatory nature, using a binary approach (yes/no) to evaluate efficac**y** (explanatory) and effectiveness (pragmatic). They acknowledged, however, that these two concepts exist on a continuum. A few years later, Thorpe et al**.** introduced the PRECIS tool to better capture this continuum across ten domains, helping researchers tailor their trials based on the desired balance between explanatory and pragmatic elements. In 2015, PRECIS-2 was re-introduced with fewer restrictions and an updated framework, allowing investigators to assess nine specific domains when designing trials, making it easier to choose the type of trial that aligns with their research goals.[1,5]

To assess whether a research study aligns more with an explanatory clinical trial or a pragmatic clinical trial, the researcher must award points based on the feasibility and applicability of each study domain. These points are assigned based on how closely the trial's design and conduct resemble real-world clinical practice. For a more explanatory trial, where the conditions are highly controlled and less reflective of routine care, lower points (closer to 1) are awarded. For a more pragmatic trial, which prioritizes real-world applicability and minimal deviation from usual practice, higher points (closer to 5) are awarded across the domains. The total score then positions the trial on a continuum, helping researchers determine whether the study is more explanatory or pragmatic.[7]

Domain 1: Eligibility

This domain defines which healthcare professionals are eligible to participate in the trial. A more explanatory trial (score of 1) would have strict exclusion criteria, limiting participation to a small, specific group of professionals. A more pragmatic trial (score of 5) would have minimal exclusion criteria, including a broader and more representative sample of professionals.[5,7]

Domain 2: Recruitment

Recruitment focuses on how healthcare professionals are enrolled in the trial. An explanatory trial (score of 1) would use extensive, time-consuming, and resource-intensive recruitment strategies, such as personalized invitations or incentives. A pragmatic trial (score of 5) would use simple and feasible approaches like announcements at meetings or word-of-mouth, reflecting real-world recruitment practices.[5]

Domain 3: Setting

The setting domain looks at the types of organizations involved in the trial. An explanatory trial (score of 1) might focus on unique or atypical organizations that are not representative of the broader healthcare landscape. A pragmatic trial (score of 5) would include a diverse, representative sample of organizations, such as hospitals or clinics across different re-

gions, to ensure generalizability.[5,7]

Domain 4: Organization

This domain refers to the resources needed to implement the trial strategies. In an explanatory trial (score of 1), resources like time, personnel, and funds would be much higher than what is typically available in real-world settings. A pragmatic trial (score of 5) would use resources that are readily accessible, such as existing quality improvement teams or electronic health records (EHRs), making it more feasible for routine care.[5,7]

Domain 5: Flexibility in Delivery

The process of intervention how it is delivered. If there is flexibility in delivery of the intervention that is details are left to the person who is going to deliver intervention in usual care it is most pragmatic practice is scoring 5 points contrarily if there is strict protocol monitoring and measuring it is most explanatory scoring 1 point.[5,7]

Domain 6: Flexibility in Adherence

If no special measure is required to ensure the compliance of the study subject to the intervention this categorized pragmatic and score 5 points on the scale. The routine measure taken by healthcare professionals in ensuring compliance as happens in the usual care does not go against the adherence flexibility. This type of trial score 5 points. If a trial requires incentives for compliance and exclusion of study subject on the basis of non-compliance it is mostly explanatory scoring one point in this domain.[5,7]

Domain 7: Data Collection

Data collection refers to the intensity and frequency of data gathered throughout the trial. An explanatory trial (score of 1) would collect frequent and extensive data, requiring significant time and effort from participants. A pragmatic trial (score of 5) would rely on existing data sources like EHRs, minimizing participant burden and reflecting real-world conditions.[5,7]

Domain 8: Primary Outcome

This domain assesses the importance of the trial's primary outcome to healthcare professionals. An explanatory trial (score of 1) would focus on proxy variables or processes that might predict effectiveness. A pragmatic trial (score of 5) would prioritize outcomes that are directly relevant to professionals and their patients, such as quality of care or patient health.[5,7]

Domain 9: Primary Analysis

Primary analysis refers to how data is used to evaluate trial outcomes. An explanatory trial (score of 1) would only analyze data from participants who completed the trial under strict conditions. A pragmatic trial (score of 5) would use an intent-to-treat (ITT) approach, analyzing all enrolled participants, regardless of whether they fully adhered to the trial protocol, to reflect real-world practices.[5,7]

After assigning scores to each domain, the total score is calculated, which measures the trial's overall position on the continuum between explanatory and pragmatic approaches. A trial that scores closer to 5 across the domains is considered highly pragmatic, meaning it is more applicable to real-world healthcare settings. This pragmatic approach reflects minimal interference with routine practice and allows the trial's findings to be easily translated into practical use in diverse, real-world environments.[1] **(See figure 1)**

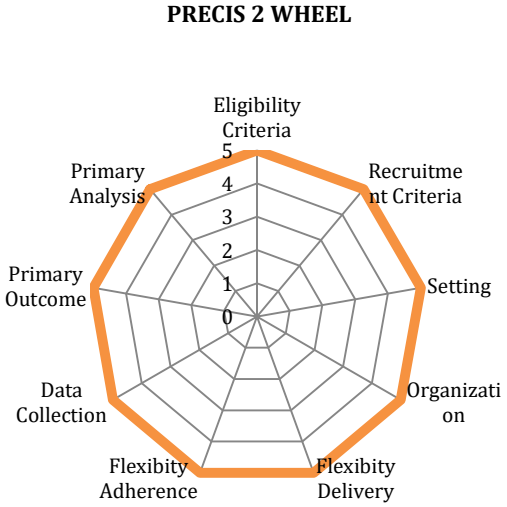

Figure 1: PRECIS 2 Wheel indicating nine domains for evaluation of pragmatic approach

Comparative Effectiveness Research (CER) and PCT are both methods used to evaluate treatment and care. CER has gained momentum over comparative efficacy studies, as it focuses on determining which treatments work best, for whom, and under what circumstances, without considering the cost of treatment with primary aim of improving patient outcomes.[8] To effectively evaluate CER, real-world data is essential, as it provides valuable insights into treatment effectiveness and helps generate evidence for informed decision-making.[9] CER, real-world evidence (RWE), and PCT are interconnected, with PCTs often leveraging real-world data to assess the practical effectiveness of treatments in everyday clinical settings, further enhancing the relevance and applicability of CER findings.[2,9] Hence, recent rise in the importance and accessibility of RWE has led to a global surge of interest in PCTs. Given this increasing global focus on PCTs, this review aims to evaluate their usage in clinical trials and assess India's awareness of this evolving research method. It also seeks to determine whether India is lagging behind other countries in adopting and implementing PCTs within its clinical research framework.

METHODOLOGY

In alignment with our objective, the authors collectively agreed to conduct a comprehensive search of clinical trial registries and databases using uniform keywords, such as "Pragmatic Clinical Trial" and "PRECIS-2 Tool." Each registry and one database were systematically examined, and relevant trials were identified based on these key terms. All retrieved data were manually entered into a Microsoft Excel sheet for further analysis, ensuring consistency and accuracy throughout the data collection process. This approach facilitated the organization and subsequent evaluation of the trials, enabling us to draw meaningful insights aligned with our research aims.

Inclusion & Exclusion Criteria: All studies related to PCT that included the keywords "Pragmatic Clinical Trial" and "PRECIS-2 Tool" were considered for analysis. We excluded studies that merely referred to a pragmatic approach or pragmatic randomized trials but did not utilize the PRECIS-2 tool or its nine domains. Additionally, studies whose designs were not fully aligned with the core principles of Pragmatic Clinical Trials were carefully excluded from the analysis. This rigorous selection process ensured that only studies truly representative of PCTs were included, thereby maintaining the relevance and integrity of the analysis.

Clinical Trial Registries: In this review, we conducted a comprehensive analysis of national clinical trial registries to evaluate the presence of studies explicitly titled "Pragmatic Clinical Trial" across various global regions. The United States emerged as a leading hub in this domain, with a notable 1,988 registered trials found in the ClinicalTrials.gov database. To refine our search, we applied several filters, including the inclusion of "Pragmatic Clinical Trial" in the study title, a study period ranging from 2011 to 2024, study locations, and study status. This rigorous approach allowed us to identify a subset of trials that fit our specific criteria.

For European clinical trials, we utilized the European Union (EU) Clinical Trials Register, employing the same keywords and filters to ensure consistency in the data collection process. This allowed us to gather a comprehensive overview of pragmatic trials registered across Europe during the specified time frame.

When assessing the landscape of pragmatic clinical trials in Asian countries, we took a regional approach by leveraging the World Health Organization's International Clinical Trials Registry Platform (WHO ICTRP) to access national registries for China. For Japan, we used the Japan Primary Registries Network (JPRN), while for South Korea, the Korea Disease Control and Prevention Agency (KDCA) and the Clinical Research Information Service (CRiS) were utilized. Each platform was searched using similar search terms and filters, enabling us to analyze trial registration trends within these nations.

For India, we employed the Clinical Trial Registry of India (CTRI), ensuring that the same keywords and parameters were applied to maintain a uniform search strategy. This methodical process across multiple platforms allowed for a thorough assessment of pragmatic clinical trial activities across key regions, providing valuable insights into the global distribution and trends of these important studies. **(See table 1).**

Table 1: Data from clinical trial registry

Country Name	Trial Registry Platform	No. of PCT
USA	ClinicalTrials.gov	1988
Europe	EU clinical trial registry	82
China	WHO international clinical trial registry platform	1
Japan	JPRN	0
South Korea	KDCA CRIS	2
India	CTRI	1

We identified 325 completed studies, 29 terminated trials, and 78 active but non-recruiting studies. This data highlights the growing prominence of PCTs in the U.S., showcasing a well-established and evolving landscape for RWE in clinical research. In contrast, Europe registered only 82 trials, revealing a significant gap in the adoption of PCTs between these developed regions. Asian countries, particularly India, are still in the early stages of adopting PCTs, with limited application in routine clinical research. Despite India's vast and diverse population, which offers great potential for generating robust RWE, the country shows minimal engagement with PCTs. This stark contrast underscores India's lag in recognizing and adopting PCTs as a valuable research tool, suggesting limited awareness and application of these trials in clinical research across the country.

Database: A search conducted in the PubMed database using the keywords "Pragmatic Clinical Trial" and "PRECIS-2 tool" for the period between 2011 and 2024 yielded 89 results. After applying filters to include only clinical trials, 12 relevant articles were identified. The highest number of publications related to PCT occurred in 2022, with 15 articles, followed by 2021, 2020, and 2018, each with 9 publications. The individual year wise publications of article were manually done by author by going through every article. This trend reflects a growing interest in PCTs among researchers. However, none of these publications were authored by researchers from India, indicating that the concept of PCTs remains relatively unknown in the country. **(See figure 2)**

When examining the publications by country, Switzerland leads with 15 publications, followed by the United States with 12 and Canada with 8.

On the other hand, countries like the Czech Republic and Austria had the fewest publications, with just one each.

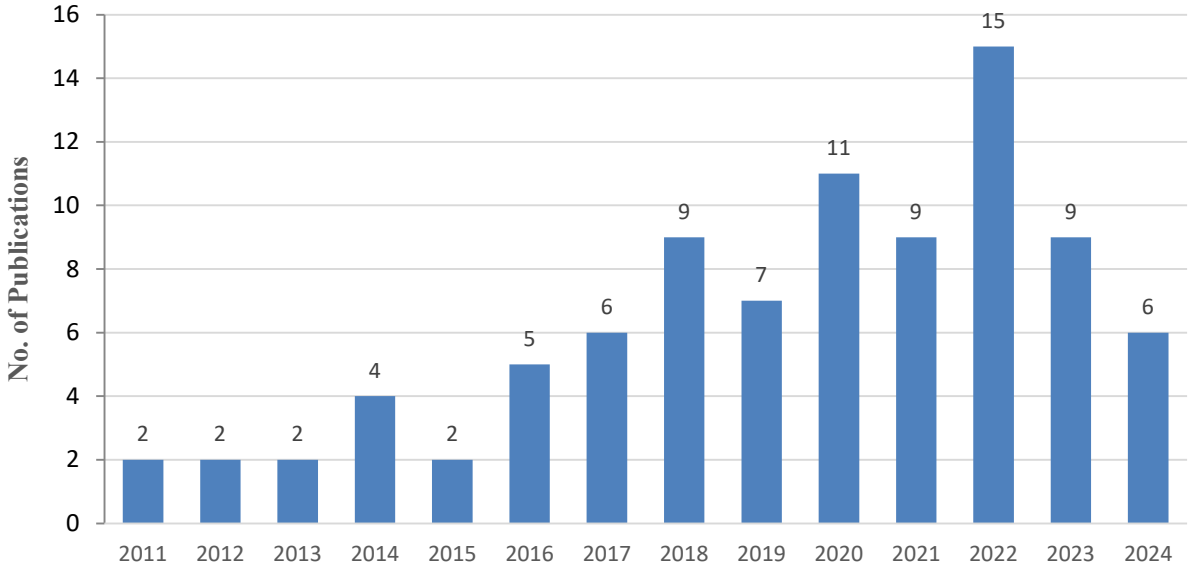

Figure 2: Number of articles published analysed from PubMed database

This distribution further highlights the regional disparities in the awareness and implementation of PCTs in clinical research. Surprisingly, when comparing clinical trial registries, South Korea has only 2 registered PCTs, while there are 4 publications related to PCTs from the country, while the US has 2,000 registered but only 12 related publications. This discrepancy highlights the possibility that some PCTs might not be fully captured in trial registries or that certain studies conducted as PCTs are not formally registered as such. It also suggests that the output of PCTs in terms of published research may exceed the number of officially registered trials, indicating a gap between conducted studies and their formal registration. Additionally, not all registered trials lead to publications, and some published studies may not have been formally registered. This highlights a need for improved transparency and alignment between trial registration and research output. **(See figure 3 & 4).** In examining regional disparities, we assessed both the trial registry data and the published literature. The United States, with nearly 2,000 PCTs, clearly leads the field, driven by a robust infrastructure supporting RWE research. Europe, despite being a highly developed region, lags behind the U.S., reflecting possible structural or regulatory barriers to PCT adoption. In Asia, particularly in countries like India, the low number of PCTs and related publications underscores limited awareness and application of pragmatic research methodologies. These findings highlight the varying degrees of PCT adoption globally, and the need for more extensive awareness and infrastructure development, particularly in countries like India, to bridge the gap in PCT implementation and research output.

Statistical Method: For the analysis of data collected from various clinical trial registries and databases, we utilized descriptive statistics and a comparative framework to identify trends, regional disparities, and the distribution of PCTs across countries. Frequency counts and percentages were employed to quantify the number of PCTs registered in each country, and year-wise trends were analysed to observe the progression of trial registrations and publications from 2011 to 2024. A comparative analysis was conducted to examine regional variations, with the U.S. serving as the benchmark due to its large number of registered PCTs. Additionally, discrepancies between the number of PCTs registered and related publications were analysed to highlight gaps between trial registrations and their dissemination in scientific literature, particularly in countries like South Korea and the U.S. This comprehensive statistical and comparative approach allowed us to identify regional disparities in PCT adoption and revealed a need for greater transparency and alignment in PCT reporting and research output globally.

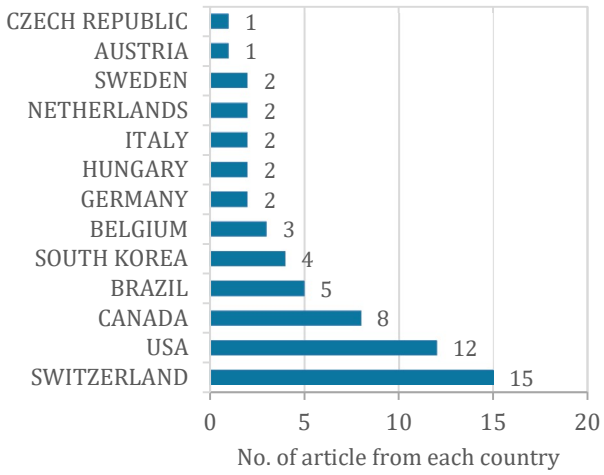

Figure 4: Number of publications country wise

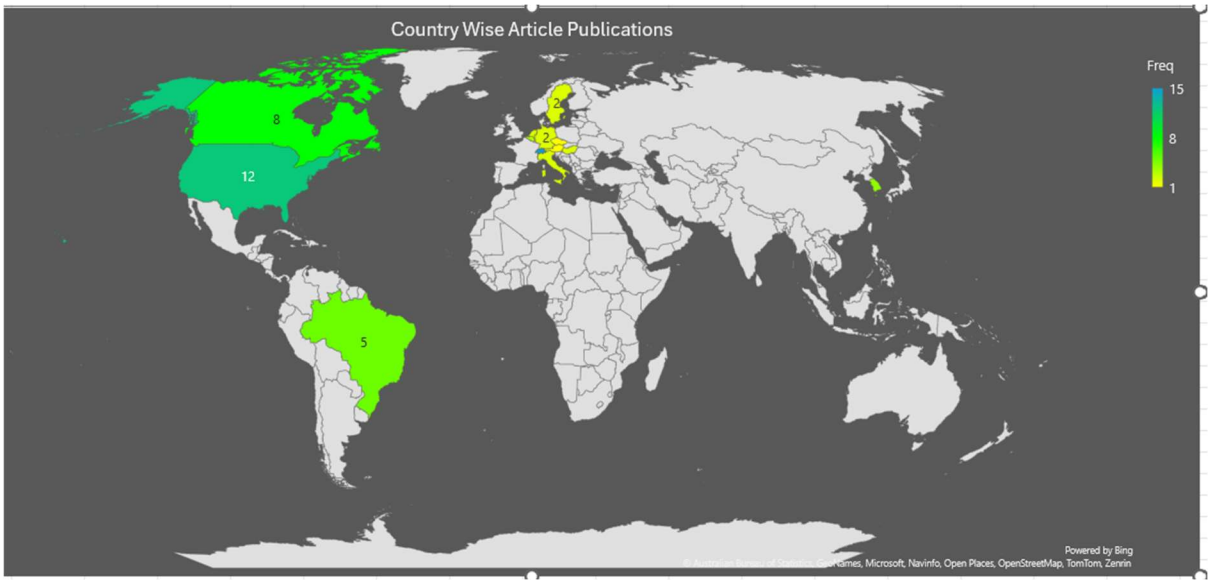

Figure 5: Nationwise PCT publication

DISCUSSION

India has become a hub for clinical trials due to its large patient pool, diverse disease spectrum, ethnically varied populations, English-speaking healthcare professionals, low costs, and strong medical and IT infrastructure, contributing 6.2% to global clinical trial activity. In contrast, other developing countries face challenges such as difficult commuting in Indonesia, communication barriers in Africa, and high trial costs and language barriers in Western Europe. These factors have led many multinational pharmaceutical companies to outsource clinical trials to India. However, despite India's growing clinical trial industry, it has faced challenges related to noncompliance with regulations and reports of unethical practices, even after several regulatory amendments. In 2013, regulations stipulated that compensation for trial injuries would have to be paid regardless of whether drugs used in the trial were the cause of injuries, and the National Pharmaceutical Pricing Policy 2012 by the government of India has resulted in margins erosion from 20% and 10% to 16% and 8% for retailers and stockists respectively. In addition to the growth challenges, the pharmaceutical industry was grappling with a number of issues like delays in clinical trial approvals, uncertainties over the FDI policy, the new pharmaceutical pricing policy, a uniform code for sales and marketing practices and compulsory licensing, all of which need a speedy resolution. The industry was also facing stricter regulations on manufacturing and quality practices in the domestic as well as the international market.[10]

Regulatory reforms in 2019 have further enhanced the landscape by reducing bureaucracy and creating new opportunities.[11] In response, the Indian government has implemented stricter oversight mechanisms, driven by investigations, media scrutiny, NGO involvement, Supreme Court hearings, and expert committee recommendations. Clinical study designs in India now encompass both experimental and observational studies, with the primary goal of establishing the safety and efficacy of new interventions. Trials also explore the long-term effects or cost-effectiveness of already approved treatments.[12,13]

While India has primarily focused on explanatory trials, there is an increasing need to shift toward PCTs that integrate real-world data, flexible protocols, and diverse populations. PCTs can play a crucial role in conducting clinical trials, particularly in ideal scenarios, as their design is tailored to the stage of development of the intervention and the desired level of pragmatism, which enhances the generalizability of the results. This approach often requires modifications to standard aspects of RCTs to improve feasibility. PCTs typically involve a heterogeneous population with minimal selection criteria and a wider age range, in contrast to explanatory trials, which tend to involve a more homogeneous and highly selected cohort sharing a common pathology. Although both trial types use a control group, PCTs often incorporate another active arm, frequently a standard-of-care group rather than a placebo group. Additionally, endpoints in PCTs are usually patient-centered-such as mortality, hospitalizations, symptoms, disability, and quality of life-facilitating data collection through more flexible surveillance systems. The increasing use of PCTs in clinical research provides valuable evidence about interventions in real-life circumstances, which is critical for new interventions, development processes, and public health decision-making. For PCTs to be effective, their correct implementation must include robust statistical design, high-quality data collection, and comprehensive follow-up to enhance their validity.[14]

Despite having highly skilled healthcare professionals, PCTs remain under-recognized in India.[15,16] The lack of Indian publications using the PRECIS-2 framework highlights a gap in awareness. Raising understanding about PCTs and their potential to

generate real-world evidence is critical for improving public health outcomes. Leveraging these reforms is essential for advancing therapies, and collaboration among government, regulatory bodies, industry, and academia is crucial for refining clinical trial policies. International partnerships also support knowledge exchange, technology transfer, and capacity building, strengthening India's role in global clinical research.[15] Still there are some complexities in clinical trial operationalization in India, such as lack of adequately trained staff, extensive workload, inadequate s pace allocated for operations, and a scarcity of administrative support.[17]

Countries like Canada have made significant progress with PCTs, conducting over 250 trials, including the ReACT PCT with more than 3,500 patients. Historical trials, such as the polio vaccine trials in the 1950s, underscore the long-term public health benefits of PCTs.[18] More recent ePCTs, supported by the NIH Collaboratory, address pressing health concerns, further demonstrating the model's value.[19] The Pragmatic Research and Innovation through Multinational Experimentation in 9 countries (PRIME-9), including Sweden, Canada, Denmark, the UK, the USA, the Netherlands, Germany, Australia, and New Zealand, has established a collaborative platform for conducting pragmatic randomized controlled trials (pRCTs). Their first initiative, the STICH 3.0 trial (NCT05761067), focuses on comparing coronary artery bypass grafting (CABG) with percutaneous coronary intervention (PCI) in patients with heart failure with reduced ejection fraction (HFrEF). This trial serves as both a visionary and achievable goal, laying the groundwork for continued global collaboration.[20]

A significant gap exists between the U.S. and Europe's adoption of PCTs and that of India and other Asian countries. The U.S., with nearly 2,000 registered PCTs, benefits from strong infrastructure and regulatory backing for real-world evidence (RWE). In contrast, India has only one registered PCT, despite its potential for generating valuable real-world data. This disparity suggests India is underutilizing its vast and diverse population in clinical research. The disparities in Pragmatic Clinical Trial (PCT) registrations across countries are influenced by several factors, including healthcare infrastructure, regulatory environments, research funding, and the adoption of real-world evidence (RWE) methodologies. The United States leads with 1,988 registered PCTs, driven by a robust research infrastructure, support from the FDA, and extensive funding, making the U.S. a global hub for PCTs. Europe, with 82 registered trials, faces challenges due to its fragmented regulatory landscape and slower adoption of RWE. China and Japan have minimal PCT activity, with 1 and 0 trials, respectively, as their clinical research environments prioritize traditional randomized controlled trials (RCTs) over PCTs, and regulatory frameworks for pragmatic trials are still evolving. South Korea, with 2 PCTs, and India, with 1, are in the early stages of adopting PCTs, hindered by a focus on conventional trials, regulatory conservatism, and lower institutional support for RWE. These differences reflect the varying levels of awareness and integration of PCTs and tools like PRECIS-2, underscoring the need for greater global standardization and capacity-building to enhance the adoption of PCTs in regions where real-world evidence could be highly beneficial.

To capitalize on PCTs, India must train researchers in PCT design, revise regulations to accommodate real-world data, and foster international collaborations. Infrastructure development in rural areas, supported by public-private partnerships, will also be vital.[20] Although RWE is gaining momentum globally, many regulatory agencies remain skeptical due to the lack of randomization, concerns over data generalizability, and risks of bias. Overcoming these barriers will require greater transparency in study design, data sources, and reporting practices.[21]

In general, the global rise in PCTs between 2011 and 2024, driven by RWE and advances in digital healthcare, offers a roadmap for India to follow. Addressing regulatory, infrastructural, and educational barriers could enable India to embrace PCTs, positioning it as a key player in global clinical research. This shift would benefit public health by providing more effective, scalable interventions. As healthcare costs rise and quality measures lag behind in India, there is a growing demand for cost-effective solutions. PCTs offer a way to assess real-world effectiveness without relying on placebo-controlled trials, helping clinicians and policymakers make informed decisions. Moving forward, India has the potential to focus on real-world care and contribute to more impactful clinical research.[22]

The PRECIS-2 framework allows Indian clinical trial researchers to design more pragmatic trials that align with the country's healthcare needs, particularly for prevalent diseases. This approach increases generalizability by using less strict inclusion criteria and adopting real-world evidence trials. This results in evidence that is more applicable to everyday clinical scenarios across India's diverse population. The data produced is more relevant for healthcare providers and policymakers, informing treatment guidelines and public health strategies. PCTs can be conducted at lower costs, making trials more feasible in resource-constrained environments like India. The focus on real-world endpoints such as quality of life and symptom management ensures that trials reflect the priorities of patients and healthcare systems, thereby improving the clinical relevance of the data.[18] Quality-of-life outcomes are crucial in cost-effectiveness analyses, a key aspect of pragmatic trials, as demonstrated in studies like MI FREEE and the Initial Antidepressant Choice in Primary Care trial comparing fluoxetine with tricyclic drugs. However, collecting quality-of-life data poses challenges in no-consent trials, such as MI FREEE, or in trials that rely on follow-up through registries or electronic health systems, like High-STEACS31 and TASTE26, unless this data is routinely recorded.[23–25]

The limitations and inherent challenges of PCTs within the specific context of India's clinical research landscape are significant. Firstly, there is a lack of empirical evidence on the generalizability of PCT results across different populations and clinical settings, both within India and internationally. This raises concerns about the external validity of PCT findings, particularly when applied to diverse healthcare systems. Furthermore, the limited awareness and implementation of PCTs in India, as evidenced by the scarcity of studies utilizing frameworks like PRECIS-2, indicate that the country's research infrastructure may not yet be fully equipped to support widespread PCT adoption.[26] Lastly, despite the emphasis on the cost-effectiveness of PCTs, conducting large-scale, long-term trials in resource-constrained environments presents financial and logistical challenges, complicating efforts to enhance the generalizability of trial results. These factors collectively limit the ability to fully assess the utility and applicability of PCTs in India's clinical research environment.[8,26]

As part of our initiative to integrate PCT into routine clinical practice, we are conducting a comparative effectiveness study evaluating antidiabetic and antihypertensive therapies, with or without statins, in patients with type 2 diabetes mellitus and hypertension. This study adopts a PCT approach, generating real-world evidence on which therapies deliver the most benefit to patients. The key advantage of a PCT is that researchers do not intervene; instead, they focus on analysing and drawing conclusions based on treatments administered by clinicians in real-world settings. This design requires a larger sample size and multicentre participation to yield robust and meaningful results.

Further, to bridge the gap in PCT adoption in India, several key steps are essential. These include streamlining regulatory processes, providing clear guidance from ethics committees, and offering increased funding support.[15] Collaborating with global networks, fostering public-private partnerships, and leveraging digital technology will also be critical.[27] Strengthening electronic health records and healthcare databases, along with regular workshops, certification programs, and continued education on PCT methodologies, can help build local expertise and enhance trial quality.[28] Additionally, establishing centralized hubs for PCTs, similar to clinical research centers, would provide the necessary infrastructure for trial coordination, data collection, and analysis.[29] By taking these actions, India can develop a strong PCT ecosystem that fosters collaboration, improves clinical outcomes, and aligns with global research standards.

Conclusion

Overall, this review highlighted the gap in implementation and lack of PCT in the routine clinical settings. In general, while India's engagement with PCTs remains limited, the potential for growth is immense. By leveraging its population diversity, reforming its clinical trial regulations, and investing in infrastructure and training, India can bridge the gap and advance the use of PCTs in clinical research, enhancing both domestic and global healthcare outcomes.

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