2026

PAKISTAN

CLINICAL RESEARCH LANDSCAPE

BMY Health

ACRP
Ambassadors Club Pakistan

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MESSAGES FROM THE REPRESENTATIVES

Syed Mustafa Kamal
Federal Minister for National Health Services, Regulations, & Coordination, Government of Pakistan

"You cannot build a resilient healthcare system without a strong foundation in clinical research, especially as Pakistan faces a growing burden of both infectious and chronic diseases. The Government of Pakistan fully recognizes that a thriving clinical trial sector improves public health, drives medical innovation, and boosts economic growth. We are firmly committed to supporting this ecosystem by empowering the regulatory & ethical bodies & encouraging strong public-private partnerships. By investing in our research infrastructure today, we are ensuring that the people of Pakistan have access to safe, advanced, and life-saving treatments tomorrow."

"At DRAP, our focus has been to make regulatory processes faster and more transparent without ever compromising patient safety. The PCRL 2026 captures this evolution, highlighting how digital systems have drastically cut down approval timelines to meet global expectations. Yet, speed is only half the equation; ensuring ethical, world-class oversight is just as critical, whether we are supporting local developments or international trials. This document serves as a roadmap, and we are proud to work alongside our academic and industry partners to ensure regulatory excellence remains the strong foundation of Pakistan's clinical research sector."

Dr. Obaidullah
Chief Executive Officer, Drug Regulatory Authority of Pakistan (DRAP)

Dr. Baber Saeed Khan
Founding President, ACRP Ambassadors Club Pakistan | Director, CTU, NUMS

"The PCRL 2026 proves that we are finally turning our untapped clinical research potential into measurable action. At the key stakeholders' level and the ACRP Ambassadors Club, our goal is to pair the natural demographic advantages with globally recognized standards. We have moved past basic capacity building and are now actively establishing the multicenter networks needed to run complex trials. By investing in our workforce and research infrastructure, we are showing the world that Pakistan is expected to be a regional hub for clinical research. I am incredibly proud of our researchers and partners who are working tirelessly to make this vision a reality."

ACKNOWLEDGMENTS

The Pakistan Clinical Research Landscape 2026 document stands as a testament to the power of multi-institutional synergy and a shared vision for the future of healthcare. This comprehensive document would not have been possible without the unwavering support, expertise, and collaborative spirit of our esteemed national partners.

The Pakistan Clinical Research Landscape (PCRL) initiative owes its inception to the pioneering efforts of **Dr. Bushra Anwar** (Director, BMY Health - Canada & Pakistan) and **Dr. Syed Uzair ul Ghani** (Chairperson, APPNA MERIT Research Subcommittee). We sincerely thank them for their foresight, guidance, and dedication to advancing clinical research in Pakistan.

We extend our deepest gratitude to the Ministry of National Health Services, Regulations, and Coordination and the National Institute of Health (NIH) for their strategic oversight and foundational commitment to advancing national health security through evidence-based research. We also express our profound appreciation to the Drug Regulatory Authority of Pakistan (DRAP) for its relentless pursuit of regulatory excellence, which continues to pave the way for a more agile and globally competitive clinical trial ecosystem in Pakistan. Furthermore, we are deeply indebted to the National University of Medical Sciences (NUMS) and the ACRP Ambassadors Club Pakistan. Their academic leadership, dedication to capacity building, and tireless efforts to implement world-class clinical standards have been instrumental in transforming Pakistan's clinical research potential into a tangible reality.

Finally, we sincerely thank the dedicated researchers, peer reviewers, and clinicians across different organizations who contributed their time and insights to this report. Your collective dedication to bridging local expertise with global standards is actively shaping Pakistan into a premier regional hub for clinical innovation. Thank you for your enduring commitment to advancing the frontiers of medicine and patient care.

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The successful compilation of the Pakistan Clinical Research Landscape 2026 document is the result of the dedication, expertise, and collaborative efforts of numerous professionals across the regulatory, healthcare, and clinical research sectors. We gratefully acknowledge the following individuals for their invaluable contributions:

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INTRODUCTION

The Pakistan Clinical Research Landscape (PCRL) 2026 document arrives at a defining moment for the nation's healthcare and life sciences sector. For decades, Pakistan's clinical research environment was characterized by its immense, largely untapped demographic potential, coupled with systemic fragmentation and regulatory bottlenecks. Today, as documented throughout this document, that narrative has fundamentally shifted. Pakistan is successfully transitioning from a peripheral data consumer into a highly sought-after, strategic partner for global multi-regional clinical trials (MRCTs).

This rapid evolution is driven by unprecedented multi-institutional collaboration and aggressive digital transformation. With a population exceeding 250 million, Pakistan offers one of the world's largest, most genetically diverse, and treatment-naïve patient bases. This demographic dividend is now being matched by a rapidly maturing infrastructure. The 2026 census data indicate an ecosystem comprising 71 licensed Clinical Trial Sites, 26 operational Contract Research Organizations, and state-of-the-art Bio-Analytical Laboratories capable of executing complex Clinical Trials.

Central to this transformation is the strengthening of national regulatory and ethical frameworks. The Drug Regulatory Authority of Pakistan (DRAP), through the enforcement of the Bio-Study Rules and the rollout of the Pakistan Integrated Regulatory Information Management System (PIRIMS), has successfully compressed regulatory timelines, bringing them in line with global expectations. Concurrently, the National Bioethics Committee (NBC) has revolutionized ethical oversight through the end-to-end digitization of the NBC-R portal, ensuring that rapid approvals never come at the expense of patient safety or scientific integrity.

Driven by the ACRP ACP initiative, this PCRL 2026 document was created by bringing all key stakeholders together in one place to collaboratively shape its contents. A collaborative endeavor by DRAP, NIH, NUMS, and leading academic and commercial institutions serves as both a situational analysis and a strategic roadmap. It highlights critical milestones achieved in regulatory agility, digital health readiness, and capacity building, while candidly addressing the hurdles that remain, such as the need for widespread EMR standardization and AI integration. Ultimately, the PCRL 2026 document demonstrates that Pakistan is no longer merely preparing for the future of clinical research; it is actively shaping it.

Regulatory Progress in Clinical Trials in Pakistan: Recent Advances & Future Opportunities

Dr. Muhammad Akhtar Abbas Khan, Director, Pharmacy Services Division, DRAP, Islamabad

Introduction:

Clinical trials are fundamental to developing safe and effective medicines, vaccines, and medical devices, yet their implementation requires significant resources (Patel, Liu, and Jena 2026; Kandi and Vadakedath 2023). A robust regulatory framework is essential to ensure scientific integrity, participant protection, and public confidence. Historically, clinical research in Pakistan suffered from fragmented oversight, limited regulatory capacity, and the absence of a dedicated legal framework (Mumtaz et al. 2024; Irumnaz and C. Nair 2014). The establishment of the Drug Regulatory Authority of Pakistan (DRAP) and the Bio-Study Rules 2017 have substantially strengthened the clinical research environment.

Development of the Regulatory Framework

The introduction of the Bio-Study Rules 2017 marked a significant milestone in the regulation of clinical research in Pakistan under the DRAP Act 2012. These rules established the first dedicated legal framework for the conduct and oversight of clinical trials, bioavailability and bioequivalence studies, clinical trial sites, and contract research organizations. The regulations introduced clear requirements for authorization, monitoring, inspection, and reporting, thereby reducing uncertainty for investigators and sponsors (Government of Pakistan 2018, 2012).

A key institutional advancement under the Bio-Study Rules was the establishment of the Clinical Studies Committee (CSC) as the principal body responsible for reviewing and approving clinical trial applications.

The committee evaluates the study protocols, assesses compliance with GCP standards, and ensures that proposed research adequately protects participant safety and welfare. This structured review mechanism has improved regulatory transparency and accountability while facilitating more consistent decision-making. (Government of Pakistan 2026, 2018).

Ethical oversight has also been strengthened by requiring all clinical trials to obtain prior approval from the National Bioethics Committee (NBC).

This framework reinforces adherence to internationally recognized ethical principles, including those outlined in the Declaration of Helsinki and the International Council for Harmonisation (ICH) guidelines. (DRAP 2026b; National Institute of Health 2026).

One of Pakistan's key regulatory achievements has been aligning its clinical research framework with international standards. DRAP incorporates principles from the World Health Organization (WHO) and ICH-GCP guidelines, enhancing the quality and credibility of clinical trial data and supporting participation in multinational research. DRAP has also issued guidelines for Conducting Clinical Research and for GCP Inspections and Reporting in Pakistan (DRAP 2025).

Pakistan's Clinical Research Landscape

Pakistan has registered 107 interventional clinical trials across 12 therapeutic categories, of which 64 are multi-Regional Clinical Trials (MRCTs), conducted across eight major cities in the country (Figure 1).

Figure 1: Pakistan's Clinical Trial Landscape

Clinical trial activity is geographically concentrated in a few urban cities; expanding trial sites to additional regions could improve national trial accessibility and site & participant diversity. Pakistan's clinical research ecosystem is supported by a blend of global and local CROs, with pharmaceutical industry sponsorship serving as the primary driver of trial activity, complemented by meaningful contributions from academic institutions & non-governmental organizations. Approximately 60% of the trials are multi-regional, and the predominance of international sponsors indicates growing global confidence in Pakistan's research capabilities.

Pakistan's clinical research portfolio is predominantly focused on infectious diseases, which account for 61% of registered trials, reflecting the country's major public health priorities and ongoing disease elimination initiatives. COVID-19 and viral hepatitis represent the largest indication clusters. International sponsors demonstrate a strong focus on infectious diseases, women's health, and oncology, whereas nutrition and metabolic research remain largely driven by local stakeholders, highlighting areas for future collaboration and capacity development. The phase distribution of registered clinical trials indicates a predominance of Phase III trials comprising 62% of the portfolio, followed by Phase II trials (22%) (Figure 2).

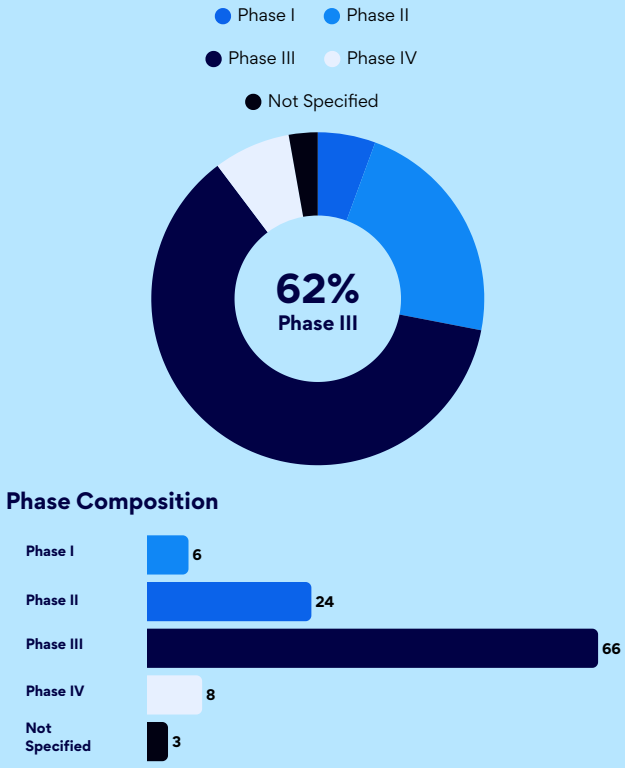

Figure 2: Clinical Trials by Phase of Development

Recent Regulatory Reforms

More recently, DRAP initiated stakeholder consultations to revise the Bio-Study Rules, 2017, to align the regulatory framework with evolving international regulatory science, recommendations from the WHO Global Benchmarking Tool, and implementation experiences. The proposed amendments seek to modernize terminology, streamline regulatory processes, and reduce approval timelines while ensuring the protection of trial participants and maintaining data integrity. Key proposed measures include expanding multidisciplinary representation on the Clinical Studies Committee and establishing a dedicated licensing framework for Investigational Product Storage & Management Sites (IPSMS), thereby strengthening oversight and operational capacity within the clinical research ecosystem (DRAP 2026c).

DRAP's planned digital platform for parallel submissions to the National Bioethics Committee (NBC) and DRAP aims to facilitate integrated ethics-regulatory review, improve transparency, and shorten approval timelines in line with global best practices. Further strengthening of institutional capacity, GCP training, risk-based monitoring, pharmacovigilance, and post-trial surveillance systems will be essential to support the efficient and sustainable growth of clinical research as trial volume and complexity increase.

Why Pakistan for Global Clinical Research

With a population of approximately 255 million, Pakistan is the world's fifth most populous country (UNFPA 2025), characterized by a young demographic profile with a median age of around 21 years (GeoRank 2026). This provides access to large, relatively treatment-naïve patient populations, alongside a substantial burden of communicable and non-communicable diseases, GCP-compliant health care institutions, and well-trained, English-speaking investigators. The clinical research environment is supported by regulatory oversight through the DRAP Act, 2012, and Bio-Study Rules, 2017, complemented by a national clinical trial registry (DRAP 2026a) and a GCP inspectorate aligned with ICH E6 (R3) guidelines (International Council for Harmonization 2025). Collectively, these factors position Pakistan as a promising setting for high-quality clinical research addressing both national health needs and global therapeutic development priorities.

Conclusion

Pakistan has made notable progress in clinical trial regulations with the Bio-Study Rules, the Clinical Studies Committee, enhanced ethical oversight, and alignment with international standards. Recent amendments and stakeholder consultations indicate a commitment to regulatory modernization. Continued investment in regulatory science and research could elevate Pakistan's role in regional and global clinical research.

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Enhancing Patient Protection and Ethical Oversight in Pakistan's Clinical Research Landscape

Dr. Faiza Bashir, Research Director & National Focal Person, National Bioethics Committee, HRI, NIH

1. Executive Summary

The National Bioethics Committee (NBC), operating under the Health Research Institute (HRI) of the National Institutes of Health (NIH) in Pakistan, serves as the country's apex regulatory & advisory body for research ethics. Mandated under the 2010 Gazette Notification, the NBC is responsible for the ethical review of research projects, capacity development for Institutional Review Boards (IRBs), and the formulation of national bioethics policies and guidelines.

This progress report highlights the major achievements of NBC across key strategic areas: institutional capacity enhancement, digital transformation, regulatory integration, guideline development, and project oversight. These milestones collectively represent a significant advancement in research ethics governance across Pakistan.

2. Institutional Capacity — Human Resource Development

2.1 Institutional Workforce

A key strategic priority for NBC has been the strengthening of its institutional workforce. Recognizing that robust research ethics oversight is only possible through a competent and adequately staffed secretariat, NBC has undertaken a significant expansion of its human resource base. The NBC Secretariat has grown its professional staff, including research coordinators and technical & administrative staff, to support the increased volume of protocol reviews and the committee's expanded mandate.

2.2 Technical Working Groups (TWGs)

To support specialized areas of ethical review, NBC has constituted Technical Working Groups (TWGs) comprising subject-matter experts. These groups provide technical input on complex protocols, particularly for clinical trials, electro-medical devices, infectious disease research, and data-intensive studies.

Key Outcome:

The expansion of NBC-R human resources has enabled the committee to significantly reduce turnaround times for ethical reviews, expand outreach activities to provincial IRBs, and strengthen the secretariat's capacity to administer the NBC-R Portal and manage the national IRB registry.

3. End-to-End Digitization of NBC-R Operations

NBC-R has completed a comprehensive end-to-end digitization of its operational processes, transitioning from manual, paper-based submission and review systems to a fully integrated digital platform. This transformation represents one of the most significant modernization milestones in the committee's history.

3.1 NBC-R Digital Portal

The NBC-R Portal (available at nbcpakistan.org.pk) now supports:

- Online submission of research protocols, applications, and supporting documents, eliminating the need for physical submission.
- Digital tracking of application status at every stage of the review process, providing real-time transparency to applicants.
- Automated notifications & correspondence between the NBC-R Secretariat and principal investigators (PIs) throughout the review lifecycle.
- Secure digital issuance of ethical approval letters and other official communications.
- Online submission and management of Annual Progress Reports and Final Reports for approved projects.
- A centralized repository for all forms, templates, guidelines, and advisories, freely accessible to researchers nationwide.

4. Integration of NBC-R Portal with DRAP

A landmark regulatory achievement has been the successful integration of the NBC-R Portal with the Drug Regulatory Authority of Pakistan (DRAP). This integration establishes a seamless and mandatory digital link between NBC-R's ethical clearance and DRAP's regulatory approval pathway.

4.1 Significance of NBC-R — DRAP Integration

- Ensures that no clinical trial or pharmaceutical research study receives DRAP approval without a valid ethical clearance from NBC-R, reinforcing the primacy of ethics in research regulation.
- Enables real-time verification by DRAP of the ethical approval status of research protocols, reducing duplication, administrative burden, and the risk of unapproved studies proceeding to regulatory review.

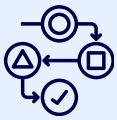
- Facilitates better inter-agency coordination between the health research ethics and drug regulatory functions of the Government of Pakistan.
- Strengthens Pakistan's compliance with international standards for Good Clinical Practice (GCP) and ethical oversight of clinical trials.

4.2 Communication and Compliance

A formal Communication with the DRAP Office Order has been issued and is publicly available, formalizing the institutional arrangement for portal integration and the mandatory requirement for ethical clearance in DRAP-regulated research activities.

5. Guidelines and Frameworks Developed

NBC has invested substantially in the development of comprehensive policy guidelines and regulatory frameworks that provide structured ethical guidance for researchers, institutions, and IRBs across Pakistan. Key documents developed include:



Framework for IRB Registration with NBC: *A structured guideline and framework document has been developed that prescribes the requirements, criteria, and procedures for Institutional Review Boards to formally register with NBC-R. This framework standardizes IRB establishment and operation across public and private research institutions in Pakistan.*

Data Sharing Guidelines: *Dedicated guidelines on research data sharing have been formulated to govern the ethical handling, transfer, and sharing of research data by investigators and institutions. These guidelines align with international standards and address issues of consent, data privacy, and cross-border data transfer.*

Guidance for Managing Ethical Issues in Infectious Disease Outbreaks: *In response to the unique ethical challenges posed by emergency public health situations, NBC-R has developed specialized guidance for managing ethical issues in infectious disease outbreaks. This document provides a framework for rapid ethical review, waiver of consent, equitable access, and other critical considerations during outbreak settings.*

6. Project Approvals — NBC-R Review Record

One of the most tangible indicators of NBC-R's operational performance is the volume and quality of research protocols reviewed and approved. NBC-R has to date reviewed and issued ethical clearances for a total of 144 projects, studies, and protocols through the NBC-R review mechanism.

6.1 Scope of Approved Research

Approved projects span a diverse range of research areas, including:

- Clinical trials and pharmaceutical studies requiring DRAP-linked ethical clearance.
- Epidemiological and public health research studies conducted by national and international investigators.
- Medical device studies, including research involving electro-medical devices, are reviewed under the NBC-R Electro-Medical Device framework.
- Biomedical and health systems research studies with human subjects conducted at public and private research institutions.
- Multi-centre and international collaborative studies requiring NBC-R ethical approval as a condition of funding or regulatory compliance.

7. Conclusion and Way Forward

The achievements documented in this progress report reflect NBC's commitment to establishing and sustaining a robust, transparent, and internationally aligned research ethics governance system for Pakistan. Through strategic investments in human resources, digital transformation, inter-agency integration, and policy development, NBC has positioned itself as a capable and credible national research ethics authority.

NBC remains committed to the following priorities going forward:

- Continued expansion of the national IRB registry and capacity development support for newly registered IRBs across all provinces.
- Further enhancement of the NBC digital portal, including the development of an online IRB registration module.
- Strengthening of the DRAP-NBC regulatory integration to cover all categories of clinical research.
- Development of additional thematic guidelines, including research with vulnerable populations, artificial intelligence in healthcare, and genomics research ethics.
- Increased engagement with international bioethics bodies and participation in global research ethics networks.

The Empirical Census of Contract Research Organizations & Clinical Trial Sites in Pakistan

Syed Muhammed Ovais, Clinical Research Associate, Clinical Trials Unit, National University of Medical Sciences

Introduction:

The global clinical trials ecosystem is shifting from traditional Western markets to patient-dense regions in South Asia and Asia-Pacific (CMIC Group 2023). Research sites in North America and Western Europe face increasing administrative hurdles, high costs, complex regulations, and low recruitment and retention rates (CMIC Group 2023; Mumtaz et al. 2024). As a result, pharmaceutical sponsors are redirecting clinical trials toward emerging hubs that ensure quick cohort enrollment and strict protocol adherence without sacrificing ethical or scientific standards.

The South Asian clinical trial corridor is the fastest-growing global market, expected to double between 2026 and 2033, with a regional CAGR of 8.4% to 8.7% (Mumtaz et al. 2024). Competitors have modernized compliance interfaces, created national screening portals, and centralized regulatory support. Pakistan stands out with its population of over 250 million, offering a diverse and treatment-naïve participant base that ensures high protocol adherence (IQVIA 2024; Sherin 2023). This is further enhanced by a dual epidemiological profile of infectious diseases and chronic conditions, allowing global sponsors to conduct multi-therapeutic investigations (Mumtaz et al. 2024; Elahi et al. 2024).

The 2026 Regulatory Census

To transition Pakistan from an underutilized research destination into a competitive regional hub, an accurate, empirical evaluation of its current operational architecture is necessary. Verified administrative registries maintained by the Drug Regulatory Authority of Pakistan (DRAP) as of June 2026 reveal a tightly regulated & consolidated infrastructure baseline (Drug Regulatory Authority of Pakistan 2026a, 2026b). DRAP reports 71 licensed Clinical Trial Sites (CTS) and 26 licensed Contract Research Organizations (CROs) (Drug Regulatory Authority of Pakistan 2026a, 2026b). However, there are only 3 certified Bio-Analytical Laboratories and 2 licensed Bio-availability/Bio-Equivalence Studies Centers (Drug Regulatory Authority of Pakistan 2026c, 2026d)

The consolidated footprint of active clinical trial sites is modest compared to the national population, but its centralization is a strategic asset for quality management. This defined boundary enables stringent compliance oversight, adherence to ICH-GCP standards, and transparent audits (Hayat et al. 2024). However, about 80% of these sites are located within private or semi-private tertiary care facilities, predominantly in elite metropolitan areas like Karachi, Lahore, and Islamabad (Mumtaz et al. 2024; Elahi et al. 2024).

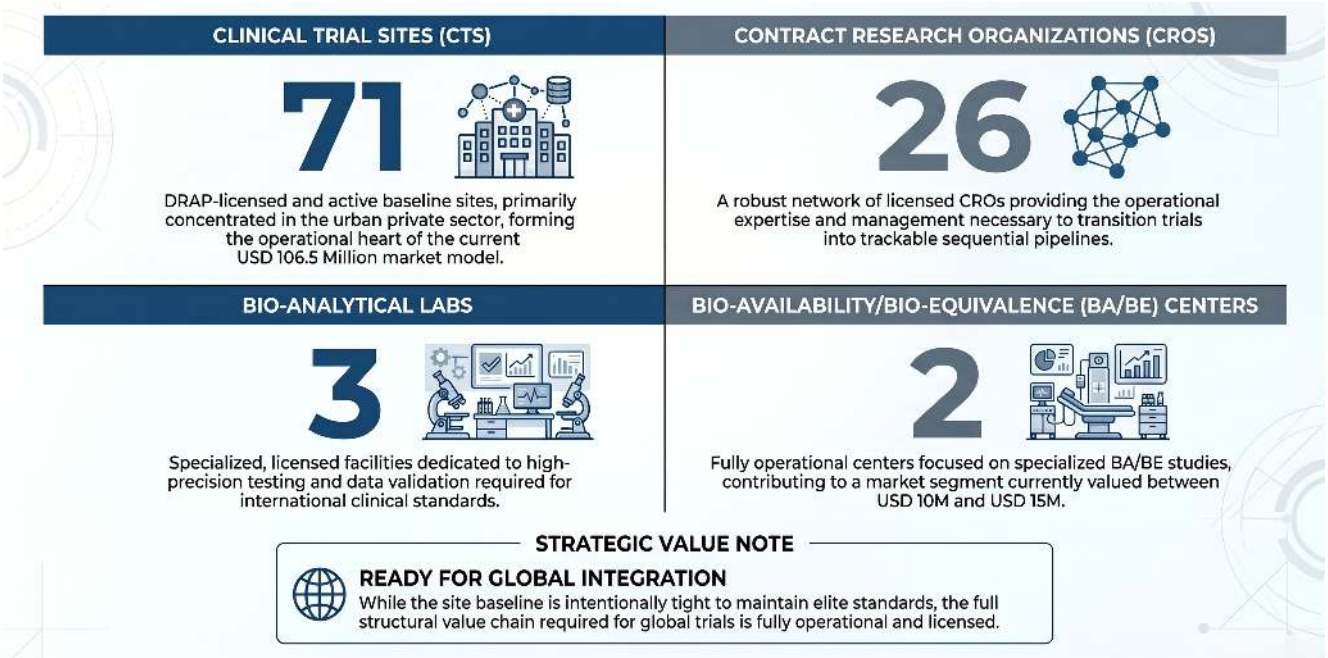


Figure 1: The Current Clinical Research Infrastructure of Pakistan

This concentration results in urban selection biases, restricts geographic reach, and excludes public healthcare settings from global scientific advancements (Irumnaz, Azizunissa, and Nair 2014; Rehman and Ahmed 2017).

To overcome these localized imbalances and achieve the necessary operational scale, Pakistan must transition from its current private-heavy baseline to an integrated national network that activates public health facilities. Across the country's administrative districts, approximately 115 public District Headquarters (DHQ) hospitals have been identified as candidates for structural and regulatory activation. By modeling their capacity based on standardized regional clinical parameters (i.e., assuming a baseline load of 10 active clinical studies per site over an operational lifecycle and a localized participant density of 10 individuals enrolled per study), the impact of expanding from a private-centric network to an integrated public-private network can be quantified:

Current Baseline Optimization:

Utilizing the existing 71 DRAP-licensed, private-heavy sites yields a maximum near-term enrollment capacity of 7,100 active participants (71 sites × 10 studies × 10 patients).

Public Sector Scaling:

Implementing a mandatory restructuring and workforce development program across all 115 public DHQ hospitals establishes an independent, state-backed research infrastructure with a capacity of 11,500 active participants (115 sites × 10 studies × 10 patients).

Integrated National Network:

Combining the current 71 optimized private sites with the 115 restructured public DHQ hospitals expands the total national research footprint to 186 licensed sites, supporting a cumulative capacity of 18,600 active participants.

This strategic expansion represents a net incremental growth of 115 functional sites and an absolute 162% expansion in nationwide participant enrollment capacity. By utilizing the public healthcare infrastructure, this integrated model systematically neutralizes the data-integrity and geographic biases inherent in the current private-sector monopoly, distributing research capabilities across 115 separate districts nationwide.

The Socio-Economic Impact

On a macroeconomic scale, the influx of international multi-center interventional studies serves as a stable source of non-debt-creating Foreign Direct Investment (FDI), enhancing national foreign exchange reserves through pharmaceutical sponsor inflows. This expansion fosters domestic job creation and knowledge transfer, requiring a workforce of certified clinical investigators, trial coordinators, clinical research associates, data scientists, biostatisticians, and lab technicians. Establishing accredited research tracks in public DHQ hospitals creates sustainable employment opportunities for medical and technical graduates, helping to mitigate the professional "brain drain" in the healthcare sector (Hayat et al. 2024; Mumtaz et al. 2024).

Moreover, this framework offers significant socio-economic benefits to public health. Activating the 115 DHQ hospitals addresses healthcare delivery imbalances by giving low-income public sector patients cost-free access to advanced treatments (Sherin 2023).

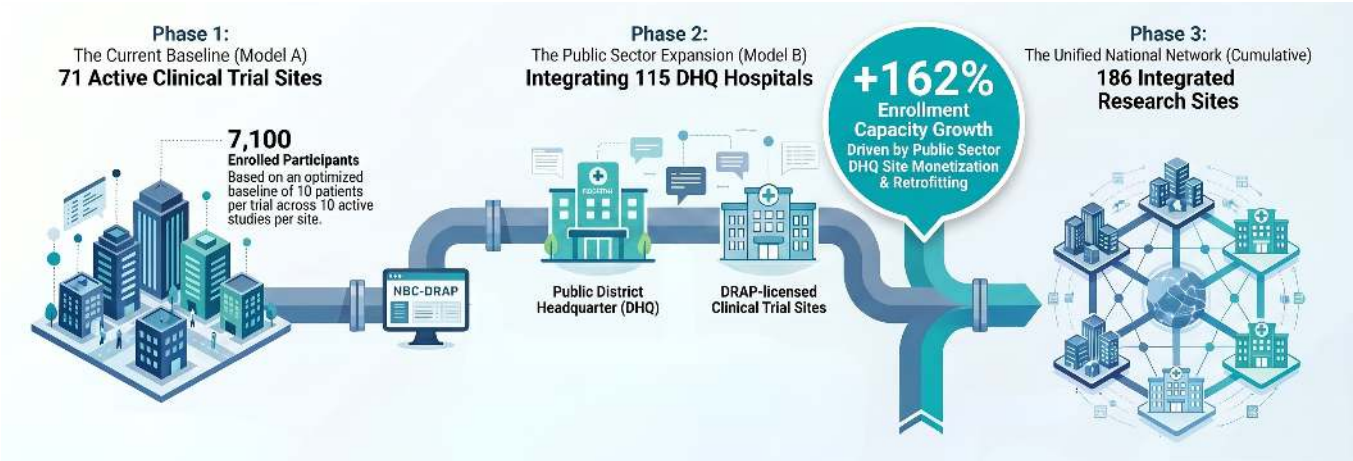


Figure 2: Phase-wise integration for Unified National Network

Additionally, international research funding upgrades government hospitals' infrastructure, modernizing diagnostic labs, improving monitoring equipment, and training staff to meet international quality standards (Hayat et al. 2024; Elahi et al. 2024).

Conclusion

The geographic shift in global clinical research presents a significant opportunity for emerging economies in South Asia. Pakistan currently has 71 clinical trial sites, 26 CROs, 3 bioanalytical labs, and 2 Bioavailability/ Bioequivalence centers, supported by the stringent oversight of DRAP. To capture a larger market share, Pakistan must transition from a concentrated urban network to a decentralized national system. By implementing a development plan across 115 public DHQ hospitals, Pakistan could increase trial sites to 186 and boost enrollment capacity by 162%. This approach would enhance sector growth, improve public healthcare, create sustainable jobs, and establish the country as a key player in global clinical research.

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How Registries Can Improve the Clinical Research Paradigm

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Randomized Clinical Trials (RCTS) are considered one of the gold standards for medical or healthcare-related decision-making (David, Patel, and Kim 2025) and have remained essential for evaluating the safety and efficacy of medicinal products before clinical use for decades. However, the limitations of relying exclusively on traditional clinical trials have been exposed by the present-day healthcare system. Clinical Trials are often time-consuming, costly, and conducted on carefully selected patient populations that may not fully reflect the diversity of patients encountered in routine clinical practice. Meanwhile, the demand for faster evidence generation, improved patient access, and data-driven healthcare decision-making is continuously growing.

One of the most persistent challenges in clinical research is the recruitment of participants who meet protocol-specific eligibility criteria. (Tan, Thomas, and MacEachern 2014) Clinical registries have the potential to address this challenge by creating structured repositories of patient information that can support research long after the initial data collection process. Medical registries have been defined as databases of identifiable individuals containing a clearly defined set of health and demographic information collected for a specific public health purpose. (Pop et al. 2018) However, modern clinical registries are far more than databases. They are prospective, structured, and continuously updated systems designed to capture meaningful information on defined patient populations, enabling researchers, regulators, and healthcare providers to generate insights that improve patient care and accelerate scientific discovery.

The importance of clinical registries has been demonstrated across diverse healthcare systems worldwide. Sweden's extensive register-based research infrastructure has established registries as a cornerstone of health research and evidence generation (Hiyoshi and Ayako 2026). India has strengthened cancer surveillance through a network of 43 cancer registries, generating critical data to support national healthcare planning and policy development (Group et al. 2025). China has further advanced registry-based research through initiatives such as the Chinese Clinical Trial Registry, reinforcing transparency and evidence-based clinical research (Wu et al. 2011).

Similarly, Iran has invested in the development and quality assessment of disease registries, highlighting the importance of robust data systems in supporting healthcare management and research activities. (Barzin et al. 2023) Together, these examples illustrate how well-coordinated registries can evolve from data repositories into strategic assets that support public health, clinical research, and evidence-based decision making.

As Pakistan seeks to strengthen its position within the global clinical research ecosystem, registries represent a strategic opportunity. While the country's clinical research landscape continues to evolve, registry development remains relatively limited and fragmented. Existing initiatives are largely concentrated within major academic and healthcare institutions in Karachi and Lahore, with only a handful of disease-specific registries operating at scale (Virani et al. 2025). Pakistan has made notable progress in cancer surveillance through the establishment of several major registries, including the National Cancer Registry, Punjab Cancer Registry, Karachi Cancer Registry, Pakistan Atomic Energy Commission (PAEC) Cancer Registry, Shifa International Hospital Cancer Registry, and Multan Cancer Registry. These registries collectively contribute to national cancer surveillance efforts coordinated through the National Institutes of Health (NIH), providing an important foundation for evidence generation and healthcare planning (Rafique and Rahat 2023).

However, most registry activities are concentrated in selected urban centers and major healthcare institutions, resulting in uneven geographical representation. To fully realize the potential of registry-based research, Pakistan requires a more integrated and nationally coordinated registry system (Figure 1) that enables comprehensive data collection across all provinces and regions. Ensuring equitable participation from healthcare facilities throughout the country would provide a more accurate understanding of disease burden, treatment patterns, and health outcomes, ultimately supporting evidence-based policy making and more effective healthcare planning.

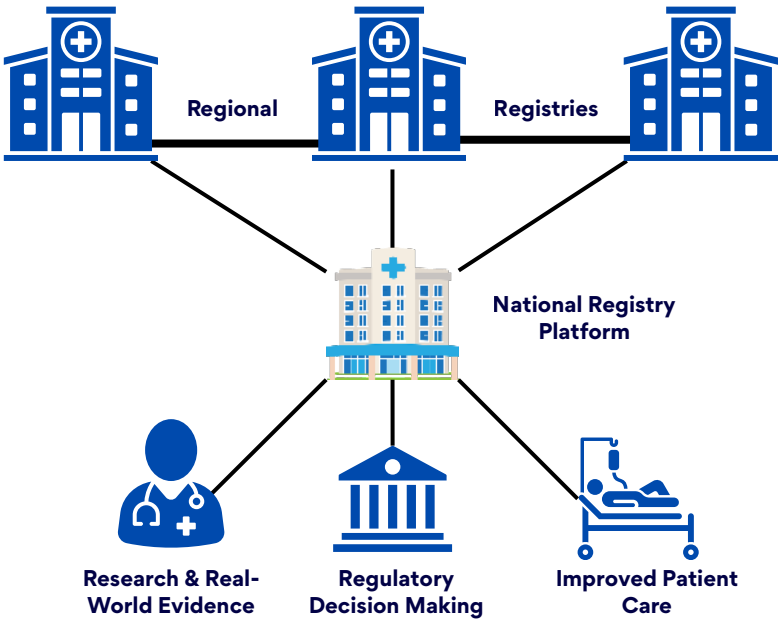

Figure 1: Proposed Framework for a National Clinical Registry Network in Pakistan

Recognizing the strategic importance of registries in evidence generation, Dow University of Health Sciences has adopted the CNEXT registry platform to establish a robust framework for long-term clinical data collection and management. The initiative is envisioned not only as an institutional resource but also as a potential contributor to national data-sharing and registry networks. By aligning institutional registry efforts with broader national objectives, DUHS aims to support the generation of high-quality real-world evidence and contribute to a more comprehensive understanding of disease patterns, treatment outcomes, and healthcare needs across Pakistan.

The success of any registry ultimately depends on patient participation. Modern registries increasingly incorporate patient-reported outcomes, enabling patients to directly contribute information regarding symptoms, treatment experiences, quality of life, and long-term outcomes. Strengthening patient awareness and ensuring consistent follow-up can significantly improve data quality and enhance the value of registries for both research and patient care.

A few ways by which the registries can transform the clinical research paradigm have been mentioned below: (Figure 2)

Figure 2: How Clinical Registries Strengthen the Clinical Research Ecosystem

i. Smarter & Quicker Patient Recruitment

Patient recruitment is often one of the most challenging and time-consuming phases involved in a clinical trial. Registries enable faster and smarter recruitment by providing access to a well-established and pre-existing patient population data. Instead of hunting and screening eligible participants across multiple sites, an investigator can competently identify suitable candidates from registry data, reducing recruitment effort and time.

ii. Long-term Outcome Tracking

Traditional clinical trials typically follow participants for a limited period. Registries, in contrast, can support longitudinal follow-up over many years, generating valuable real-world evidence regarding treatment effectiveness, safety outcomes, disease progression, and healthcare utilization patterns. Such information is essential for understanding how therapies perform beyond the controlled environment of a clinical trial.

iii. Pharmacovigilance

The identification of rare adverse events often requires observation of large patient populations over extended periods. Clinical registries can serve as powerful pharmacovigilance tools by facilitating the early detection of safety signals & supporting post-marketing surveillance activities. This capability contributes to a more comprehensive understanding of the benefit-risk profile of medicines and medical devices throughout their lifecycle.

iv. Precision Medicine

As healthcare shifts to personalized treatments, registries are essential for precision medicine. They collect clinical data, treatment histories, biomarker information, and patient outcomes to identify effective interventions for specific patient groups. In a diverse population like Pakistan's, this can enhance treatment outcomes and support individualized clinical decision-making.

v. Health Economics

Registries provide essential evidence for healthcare policy and resource allocation by delivering reliable data on disease burden, treatment outcomes, and disparities. This aids policymakers in making informed decisions about service delivery and public health, particularly in resource-limited areas. Additionally, registries offer real-world data that supports research feasibility assessments and clinical trial planning, enhancing healthcare systems' roles in global research initiatives.

vi. Regulatory Support

Clinical registries are valuable tools for regulatory authorities as they provide real-world data on the safety and effectiveness of medicines and vaccines. For Pakistan's Drug Regulatory Authority (DRAP), enhancing registry infrastructure would improve post-marketing surveillance, signal detection, and risk assessment, allowing for more effective responses to safety concerns and ensuring the quality and safety of healthcare products.

Well-established registries can accelerate innovation, strengthen collaboration between stakeholders, and support more informed healthcare decisions that ultimately benefit patients. As the country's clinical research landscape continues to evolve, the development of a comprehensive and credible registry infrastructure has the potential to enhance Pakistan's visibility on the global research stage, attract new opportunities for collaboration and investment, and position the nation as a meaningful contributor to the future of clinical research. The journey from data collection to evidence generation begins with registries, but their true value lies in their ability to transform information into better healthcare, stronger research, and lasting impact.

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Can Pakistan Become the Next Global Hub for Clinical Trials?

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Abstract

The globalization of clinical research has accelerated over the past two decades as pharmaceutical companies increasingly seek cost-effective locations with large patient populations and efficient recruitment capabilities. Emerging economies have become attractive destinations for clinical trials due to lower operational expenses and diverse disease profiles. Pakistan possesses several characteristics that support its development as a regional clinical research hub, including a population exceeding 240 million, a substantial burden of communicable and non-communicable diseases, a skilled medical workforce, and relatively low research costs. Despite these advantages, challenges related to regulatory efficiency, research infrastructure, and international integration continue to limit its competitiveness. This review examines Pakistan's strengths and limitations in comparison with regional competitors such as India, Bangladesh, China, and Gulf countries, and evaluates its potential to become a major destination for multinational clinical trials.

Introduction

Clinical research has undergone a major geographical shift from traditional markets in North America and Europe toward emerging economies. Rising development costs, increasing demand for diverse patient populations, and the need for faster participant recruitment have encouraged pharmaceutical companies to expand research activities into Asia, the Middle East, and other developing regions.

Countries such as India and China have successfully established themselves as important contributors to global clinical research through regulatory reforms, infrastructure development, and strong integration with international pharmaceutical industries. Gulf nations, particularly the United Arab Emirates and Saudi Arabia, have also invested heavily in healthcare modernization and precision medicine initiatives. Pakistan, although less established, possesses significant untapped potential due to its demographic and healthcare characteristics.

Advantages of Pakistan as a Clinical Trial Destination

One of Pakistan's greatest strengths is its large and diverse population. With more than 240 million people, the country offers access to a broad patient pool capable of supporting large-scale multicenter studies. Large populations facilitate faster recruitment, which remains one of the most critical determinants of successful clinical trial execution.

Pakistan also has a high proportion of treatment-naïve patients. Many individuals present with advanced disease stages and limited prior exposure to innovative therapies, making them particularly valuable for evaluating novel interventions. This characteristic is especially important in oncology, infectious diseases, gastroenterology, and chronic disease research.

Another significant advantage is the country's disease burden. Pakistan faces a high prevalence of cardiovascular disease, diabetes mellitus, cancer, tuberculosis, hepatitis B and C, and various infectious diseases. These conditions correspond closely with major therapeutic areas targeted by global pharmaceutical research. The availability of large patient populations affected by these diseases creates substantial opportunities for clinical studies ranging from early-phase investigations to large post-marketing trials.

Cost efficiency further enhances Pakistan's attractiveness. Clinical trials conducted in developed countries are associated with high expenditures related to hospital services, investigator fees, diagnostic testing, staffing, and regulatory compliance. Pakistan offers considerably lower operational costs while maintaining access to qualified healthcare professionals and tertiary care facilities. This cost advantage can significantly reduce overall drug development expenses for sponsors.

Skilled Medical Workforce

Pakistan possesses a strong healthcare workforce capable of supporting complex clinical research activities. Thousands of physicians, pharmacists, nurses, and allied healthcare professionals graduate annually from recognized institutions across the country.

Major healthcare centers, including Jinnah Postgraduate Medical Centre, Aga Khan University, Dow University of Health Sciences, and Shaukat Khanum Memorial Cancer

Hospital & Research Centre, provide specialized services and manage large patient volumes. These institutions also contribute to academic research and clinical training.

Many Pakistani investigators have received training in Good Clinical Practice (GCP), research ethics, pharmacovigilance, and clinical trial management. Experience gained through participation in national and international research projects has strengthened local expertise, particularly in oncology, infectious diseases, and chronic disease management. Strong English-language proficiency among healthcare professionals further facilitates collaboration with multinational sponsors and Contract Research Organizations (CROs).

Current Challenges

Despite its strengths, Pakistan faces several obstacles that limit its ability to compete with established clinical research destinations.

Regulatory processes remain one of the most significant challenges. Although the Drug Regulatory Authority of Pakistan (DRAP) has introduced important reforms and clinical trial guidelines, approval timelines may still be affected by administrative delays and limited digitalization. Efficient regulatory systems are essential for attracting international sponsors who often prioritize countries with predictable and streamlined approval pathways.

Research infrastructure also requires further development. Compared with India, China, and Gulf countries, Pakistan has fewer dedicated clinical trial units, research coordinators, biobanks, and advanced electronic data management systems. Modern clinical trials increasingly depend on sophisticated infrastructure to ensure regulatory compliance, participant safety, and data quality.

International visibility remains another limitation. Although scientific publications from Pakistani institutions have increased steadily, participation in large multinational studies remains relatively limited. Greater involvement in international collaborations would strengthen Pakistan's credibility and enhance its attractiveness to global pharmaceutical companies.

Regional Comparison

Compared with neighboring countries, Pakistan occupies an intermediate position within the regional clinical research landscape. India continues to lead South Asia due to its mature regulatory framework, extensive CRO network, advanced infrastructure, and long-standing relationships with multinational sponsors. China has emerged as a global leader through substantial investments in biotechnology, precision medicine, and research facilities. Meanwhile, Gulf countries such as Saudi Arabia and the United Arab Emirates have rapidly strengthened their clinical research capacity through government-supported healthcare modernization programs and strategic investment in biomedical innovation.

Although Pakistan currently lags behind these countries in infrastructure and regulatory maturity, it maintains several competitive advantages. Lower operational costs, reduced competition among research sites, abundant treatment-naïve patients, and a substantial disease burden provide unique opportunities for efficient patient recruitment and cost-effective trial execution.

Future Opportunities

The future of clinical research in Pakistan depends largely on strategic investments and policy reforms. Strengthening regulatory efficiency through digital submission systems and faster review processes would improve the country's competitiveness. Expanding dedicated clinical trial units, biobanks, advanced laboratories, and electronic data systems would enhance research quality and operational capacity.

Additional investment in investigator training, research mentorship programs, and academic publication initiatives could further strengthen workforce readiness. Increased collaboration with international universities, pharmaceutical companies, and CROs would also improve global visibility and facilitate knowledge transfer.

Public-private partnerships may play a particularly important role in accelerating infrastructure development and attracting foreign investment. With sustained commitment from government agencies, academic institutions, and healthcare organizations, Pakistan could significantly expand its role within the international clinical research ecosystem.

Conclusion

Pakistan possesses many of the fundamental attributes required to become a competitive regional hub for clinical trials. Its large population, diverse disease burden, treatment-naïve patient pool, skilled healthcare workforce, and cost-effective research environment provide a strong foundation for growth. However, realizing this potential will require continued improvements in regulatory efficiency, infrastructure development, international collaboration, and research capacity building. If these priorities are addressed strategically, Pakistan could emerge as an attractive destination for multinational clinical research and play a more prominent role in the future of global drug development.

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Pakistan's Emergence as a Strategic Clinical Trial Destination: A Comparative Perspective with Southeast Asia

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Benjamin Laverty, Vice President, R&D Operations, IQVIA

EXECUTIVE SUMMARY

Pakistan is the fifth most populous country in the world and carries one of the heaviest infectious and chronic disease burdens in Asia, yet it remains underrepresented in global clinical development. This paper compares Pakistan with six established Southeast Asian markets and argues that the two geographies are complementary, not competing. Southeast Asia offers regulatory predictability, early-phase depth, and mature site infrastructure. Pakistan offers something increasingly scarce: very large treatment-naïve populations, high disease prevalence, fast enrollment, and a meaningfully lower cost base, supported by GCP-trained, English-speaking investigators and a regulatory framework that now permits parallel review. Drawing on IQVIA's regional operating data and on field experience, the paper identifies the indications where Pakistan creates the most value and explains why the country deserves a defined role in regional programs.

Introduction

For the better part of two decades, sponsors designing studies in Asia have returned to the same short list of countries. Singapore, Malaysia, Thailand, Vietnam, Indonesia, and the Philippines each developed credible clinical ecosystems, and for many protocols they remain entirely appropriate choices. The variable that has shifted is patient supply. Enrolling eligible, treatment-naïve participants at the speed of competitive timelines has grown noticeably harder. Site saturation, overlapping protocols competing for the same patient pools, and improving standard-of-care reimbursement are steadily compressing recruitment in several of these established markets, often without sponsors recognizing the trend until timelines slip. This is the context in which Pakistan deserves a closer look. Its relevance to regional planning runs well ahead of its present trial volume. The case here is not that Pakistan should displace Southeast Asia; the region's strengths are real and well documented. Rather, a sponsor optimizing for speed, scale, and cost has good reason to fold Pakistan into the same regional strategy from the outset, treating it as a deliberate option rather than a late-stage contingency.

Comparative Analysis: Pakistan Vs. Southeast Asia

Population and patient access.

Pakistan's population reached roughly 251 million in 2024, the fifth largest in the world (World Bank, 2024). That base exceeds the Philippines and Vietnam combined and far outstrips Singapore's six million and Malaysia's thirty-six million (IQVIA, 2026). Scale by itself proves little. What matters more is the proportion of patients who have never received modern therapy. Because reimbursement for high-cost innovative drugs remains limited, a clinical trial is often a patient's first access to advanced treatment. That dynamic produces cleaner efficacy signals and a participant population with strong reasons to stay enrolled.

Recruitment performance.

Between 2017 and 2025, four IQVIA partner and network sites in Pakistan enrolled 780 patients into interventional trials, working from a comparatively small operational base (IQVIA, 2026). The headline figure understates the real performance. Counting all 41 IQVIA studies and the 72 sites initiated over that period, the country randomized close to 3,200 patients, a per-study yield that stands up well against markets carrying several times the active-site count (IQVIA, 2026). Having overseen recruitment across hepatology, infectious disease, and vaccine programs here, sites have demonstrated the ability to meet targets ahead of schedule while maintaining data quality despite competitive enrollment pressure.

Regulatory environment.

Here, perception trails reality. The Drug Regulatory Authority of Pakistan (DRAP) oversees trials under the Bio-Study Rules, 2017, with protocol review handled by the Clinical Studies Committee and ethics oversight by the National Bioethics Committee (DRAP, 2017). The framework now permits parallel submission to DRAP and the NBC, which shortens start-up rather than forcing approvals through one after another (DRAP, 2024). Southeast Asia still has the edge on predictability, and this position is not disputed otherwise: Singapore and Malaysia work to tighter, better-documented timelines (IQVIA, 2026). The gap, though, is closing, and for sponsors who prepare their submissions carefully, start-up is no longer the bottleneck it once was.

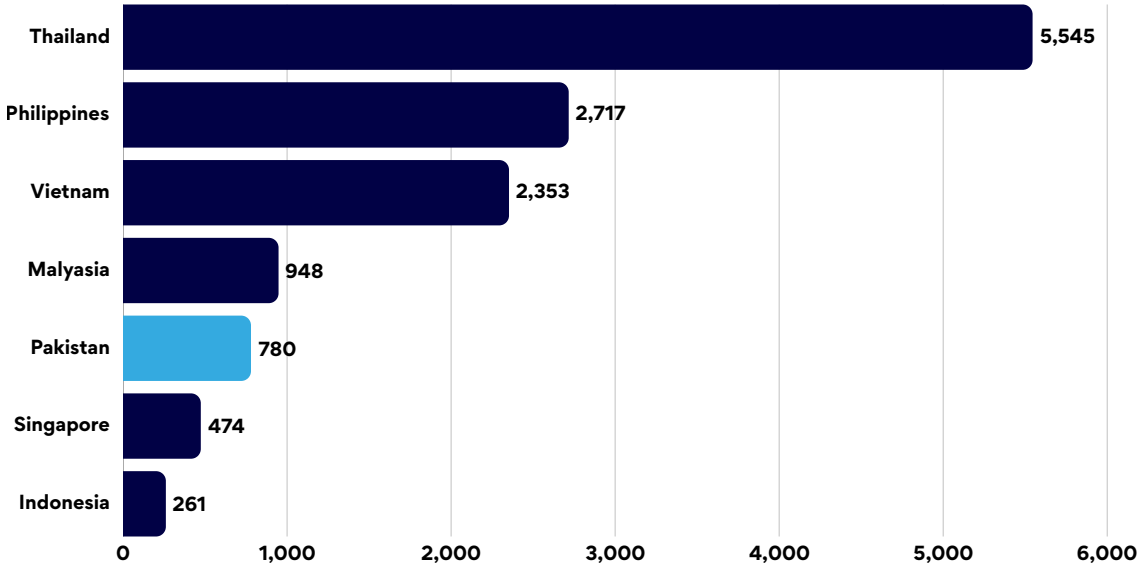

Figure 1. Patient recruitment 2017–2025 (Phase I–IIIb, excl. vaccines). (IQVIA , 2026)

Investigator and site capability.

DRAP-approved clinical trial units sit inside JCI, ISO, and CAP-accredited institutions, staffed by consultants trained in the United States, the United Kingdom, and Europe who average more than sixteen years of local experience (IQVIA, 2026). Several of these units have been inspected by the WHO and other authorities. English serves as the working language of both medicine and research, eliminating a translation step that slows monitoring and query resolution in many comparable markets.

Pakistan Sponsor-Attractiveness Profile

This profile sets Pakistan against a representative Southeast Asian benchmark across the six criteria sponsors weigh when deciding where to place a study. On each axis, a line that reaches closer to the outer edge signals greater strength on that factor. The two profiles trace noticeably different shapes, and that contrast is the point: each market is strong precisely where the other is not.

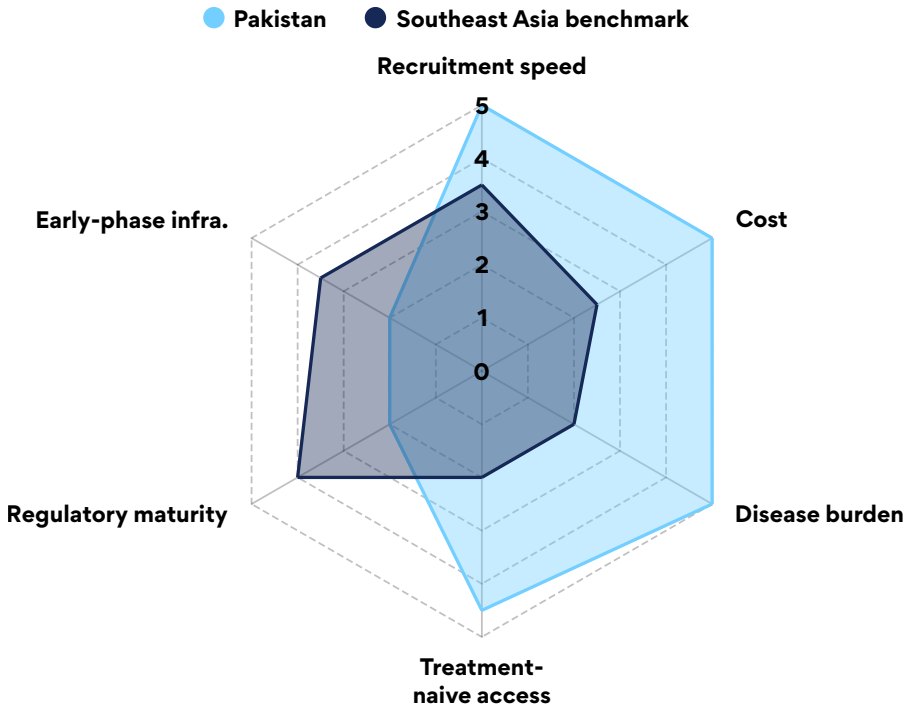

Figure 2. Sponsor-attractiveness profile, scored 0 (center) to 5 (edge).
Pakistan in light blue, Southeast Asia benchmark in dark blue.

Cost and operational efficiency.

Investigator grants, monitoring, and site costs run well below those of higher-income markets, and import duties on trial materials are eased (IQVIA, 2026). Competitive budgets paired with rapid recruitment improve trial economics from both directions, and they do so without the quality compromise sponsors are right to scrutinize.

Quality and compliance.

This is the dimension skeptics expect Pakistan to fall short on, yet the audit trail suggests the opposite. Over the past five years, third-party audits across roughly 25 IQVIA studies returned major findings in only about one percent of cases (IQVIA, 2026). By any reasonable measure, that is a strong inspection profile, and it reflects the disciplined protocol adherence typical of experienced sites.

Clinical Research Competitiveness: Pakistan vs Southeast Asia

Country	Population	Regulatory timeline	Recruitment potential	Cost advantage	Infrastructure
Pakistan	~251 M	Improving (parallel)	Very high	High	Developing
Indonesia	290 M	Improving	High	High	Developing
Philippines	>115 M	Moderate	High	Moderate	Strong
Vietnam	102 M	Improving	High	Moderate–high	Developing
Thailand	~72 M	Fast (2024 reform)	High	Moderate	Advanced
Malaysia	~36 M	Predictable/fast	Moderate	Moderate	Advanced
Singapore	6.1 M	Predictable	Low–mod	Low	Advanced

Qualitative assessment by the author, informed by IQVIA operating data (IQVIA, 2026) and World Bank population estimates (World Bank, 2024). Ratings reflect operational experience and are not standardized indices.

Figure 3. Comparative strength matrix. The author's assessment as informed by IQVIA (IQVIA, 2026).

Pakistan's Strategic Advantages

Pakistan turns a heavy disease burden into recruitable, evaluable patients more quickly and at lower cost than most countries in the region, and it does so while meeting the quality standards that global sponsors insist on. The eight factors set out below explain why the country deserves a place on any regional shortlist.

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Where Pakistan Creates the Greatest Value for Sponsors

Hepatology (HBV, HCV, HDV). This is the most clear-cut opportunity. WHO identifies Pakistan as the single largest contributor to the global hepatitis C burden, with national prevalence estimated at roughly five percent and several million people infected (WHO, 2024 & Qureshi et al., 2024). Hepatitis B is similarly widespread, and hepatitis delta runs unusually high among HBsAg-positive carriers, a population that HDV developers struggle to assemble at scale almost anywhere else (IQVIA, 2026). For HBV, HCV, and HDV programs, Pakistan offers patient numbers that few countries can rival.

Infectious disease, TB, and vaccines. Endemic tuberculosis, dengue, and malaria, combined with the capacity to enroll large healthy-volunteer cohorts, support both therapeutic and prophylactic vaccine work (IQVIA, 2026).

Cardiovascular disease, diabetes, and obesity. Heart disease and diabetes rank among the country's most prevalent conditions, enabling rapid recruitment into cardiovascular outcome and metabolic trials; obesity is an emerging area of interest (IQVIA, 2026).

Rare diseases and RWE. High rates of consanguinity raise the prevalence of thalassemia, Gaucher disease, and related disorders, giving access to cohorts that are difficult to build elsewhere. The size and diversity of the population also make real-world evidence a natural extension of trial activity (IQVIA, 2026).

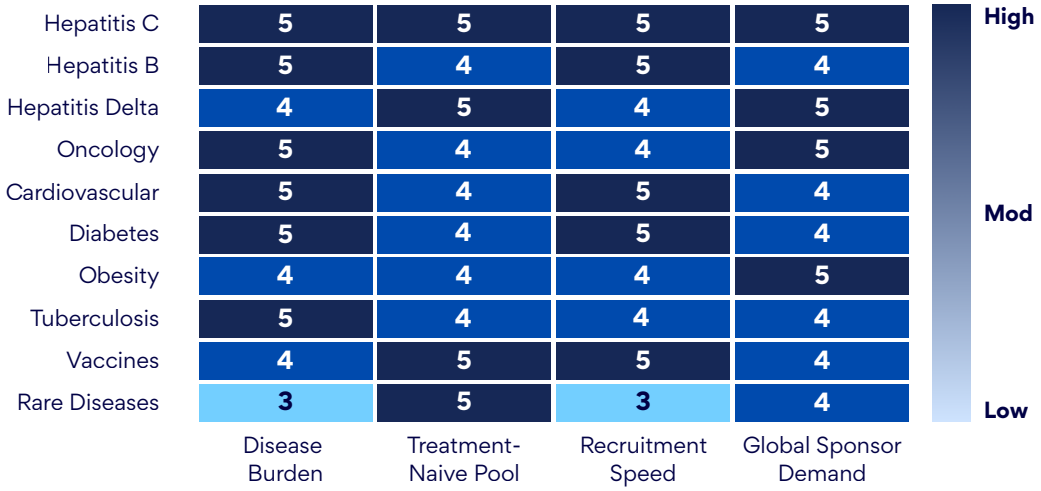

Figure 4. Sponsor opportunity matrix across high-value indications (1 = low, 5 = high).

Including Pakistan in Regional Programs

The recommendation is a practical one. Pakistan fits protocols that call for high enrollment volume, treatment-naïve patients, fast recruitment, and disciplined costs. Where a study instead demands early-phase expertise or specialized infrastructure, Southeast Asian sites are the stronger choice. Combining the two spreads the timeline risk across markets and broadens the evidence base, rather than asking any single country to carry the full program.

Future Outlook

Regulatory reform is advancing, site networks are broadening, and decentralized, technology-enabled models are gaining real traction. Yet the work is far from complete. Predictability still needs to improve, and the trial-registry infrastructure has to mature before it can carry the weight now being placed on it. What stands out is the consistency of the direction. Sponsors that build a presence at this stage will find themselves a step ahead as the system matures.

The question is no longer whether Pakistan can deliver, but where in a global program it delivers the most value

Conclusion

Pakistan has matured from an emerging market into a credible strategic partner for global clinical development, particularly in indications where rapid recruitment, heavy disease burden, and operational efficiency carry the most weight. The question was never Pakistan versus Southeast Asia. It is Pakistan, alongside Southeast Asia, with each region drawn on for the strengths it brings.

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Pakistan's Transition from Data Consumer to Global Trial Partner

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Introduction:

Historically, lower-middle-income countries (LMICs) like Pakistan have sat on the sidelines of global clinical development. Over 83% of clinical trial sites are concentrated in just 25 high-income nations, leaving fewer than 5% spread across more than 90 LMICs (Mumtaz et al. 2024). Consequently, Pakistan's healthcare system has long relied on "borrowed evidence"—therapeutic guidelines derived from genetically and socio-economically distinct Western populations.

Entering 2026, a definitive paradigm shift is underway. Driven by a regulatory overhaul by the Drug Regulatory Authority of Pakistan (DRAP), an expanding network of accredited Clinical Trial Units (CTUs), and urgent public health mandates, the country is emerging as a formidable hub for high-impact global clinical trials.

Regulatory Modernization and Global Site Performance

The primary bottlenecks to local progress—a bureaucratic regulatory loop and weak infrastructure in domestic medical schools—have been directly countered. DRAP systematically streamlined its processes, publishing updated guidelines that standardize approvals for therapeutic goods and harmonize ethical clearances.

This fast-tracked pathway has paid immediate dividends in international multi-center studies. A standout example is the global Phase 3 D-LIVR study for Chronic Hepatitis Delta Virus (HDV) infection—the largest in HDV history, spanning 116 sites across 22 countries. Led locally by the Aga Khan University Hospital (AKUH) Clinical Trials Unit, the Pakistani site surpassed recruitment targets by enrolling 53 patients while recording some of the lowest attrition rates in the entire global trial (Clinical Trials Unit 2025). This milestone proves that Pakistani sites can deliver high-integrity data matching standard Joint Commission International (JCI) benchmarks.

Targeting Hyper-Local Public Health Crises

Local research infrastructure is directly answering the call for increased domestic ownership over national health strategies, focusing on critical vulnerabilities like antimicrobial resistance (AMR) and endemic infectious diseases.

The Looming AMR Cliff

Pakistan is one of the world's highest consumers of antibiotics, driven by over-the-counter availability and self-medication. Forecasting studies published in 2026 reveal alarming trajectories from 2016 to 2023: macrolide consumption rose by 76% (projected to reach 5.79 Daily Defined Doses per 1,000 inhabitants per day [DID] by 2028), and cephalosporins increased by 36% (*Saleem 2026*). More critically, reliance on last-line "reserve" therapies like oxazolidinones (+354%) and glycylcyclines (+236%) has surged drastically (Saleem 2026).

In response, local trials are pivoting toward antimicrobial stewardship. This capacity was vital during the multi-center RIFASHORT trial, which successfully evaluated reducing pulmonary tuberculosis treatment from six months down to four using high-dose rifampicin—aligning with global mandates for shorter, all-oral regimens to block resistant mutations (Zhang 2026).

Antibiotic Class	Trend (2016–2023)	Projected (By 2028)	Operational Impact
Macrolides	+76% Increase	5.79 DID	Accelerated stewardship required
Cephalosporins	+36% Increase	Elevated Baseline	Widespread resistance pressure
Oxazolidinones (Reserve)	+354% Increase	Critical Surge	Last-line therapeutic vulnerability
Glycylcyclines (Reserve)	+236% Increase	Critical Surge	Severe restriction of fallback options

Implementation Science and Digital Integration

This research momentum has sparked a wider cultural shift. The International Conference on Health Research (ICHR) saw a 233% explosion in professional registration between 2023 and 2025, surpassing 2,000 active multidisciplinary professionals engaging with AI-integrated health research and implementation science (Ahmed 2026). This expertise aligns with the rapid digitization of Pakistani healthcare. Emerging digital health delivery frameworks, such as Sehat Kahani and Teeku Telehealth, are acting as operational testing grounds under the National Digital Health Framework 2022–2030 (Amjad 2026). This integration provides a massive opportunity to deploy decentralized clinical trials (DCTs) and capture real-world data (RWD) from remote, historically unreached cohorts.

Unresolved Frontiers:

Despite massive strides, notable regulatory and logistical blind spots remain in 2026:

Regenerative Medicine: For millions suffering from thalassemia or degenerative disorders, stem cell therapeutics are a crucial frontier. While biologicals fall under the DRAP Act of 2012 and Bio Study Rules of 2017, Pakistan lacks a specialized, multi-tiered framework to differentiate traditional tissue transplants from Advanced Therapy Medicinal Products (ATMPs) (Rehman 2026). Experts are actively lobbying DRAP to adopt advanced regional models, such as Malaysia's NPRA guidelines.

Pharmacovigilance (PV): While pre-market trial monitoring has matured, post-market surveillance and spontaneous Adverse Drug Reaction (ADR) reporting systems are still in their infancy (Hussain and Hassali 2019). Creating a seamless loop between pre- and post-market safety data remains an essential mandate to protect patient safety in a fragmented network.

Outlook for the Global Landscape

Pakistan's value proposition to the international clinical trials ecosystem is clear: a massive, genetically diverse, treatment-naive population, a maturing network of JCI-accredited investigators, and tight regulatory alignment with global guidelines. By pivoting inward to solve domestic crises like AMR and outward to anchor global Phase 3 trials, Pakistan is asserting its position as an active scientific contributor to international evidence-based medicine.

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Pakistan's Role in Global Clinical Research

Three Case Studies Across Therapeutics, Diagnostics, and Trial Operations

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The following case studies illustrate how Pakistan's clinical research ecosystem is supporting global studies across therapeutics, diagnostics, and medical devices.

Case Study 1:
Accelerating a Global COVID-19 Rescue Trial

Background

When a biotechnology company set out to develop an anti-inflammatory therapy for severe COVID-19, it found itself racing against two clocks: the pace of the pandemic and the pace of its own clinical development program. Recruitment in its international trial had stalled. With patients suffering and timelines slipping, the sponsor needed a new country that could move quickly while keeping patient safety as the top priority and remaining compliant with global standards. (Shabbir 2024)

Pakistan emerged as the answer. With globally recognized and experienced investigators, a population facing severe COVID-19, and a clinical research infrastructure that had been steadily developing for years, the country had strong potential. The question was whether that infrastructure could perform under pressure.

What Made It Difficult

The obstacles were real. Ethical and regulatory approvals that normally take months had to be compressed into weeks during an active public health emergency. The study itself was an inpatient trial involving critically ill patients, which meant any operational failure could carry serious consequences. Pandemic restrictions had also disrupted site monitoring and limited the ability of staff to perform conventional on-site duties.

In addition, global travel restrictions affected the import of investigational products, which had to cross international borders. National customs and import processes were also disrupted during the pandemic, adding further complexity during a period of global supply chain strain. Alongside this, biological specimens collected from study participants had to be shipped internationally to central laboratories while maintaining strict cold-chain conditions throughout.

What Happened

Rather than treating these as sequential problems, the sponsor and clinical research organizations addressed them in parallel. Accelerated communication channels were opened directly with ethical and regulatory bodies to support fast-track approvals. These bodies recognized the urgency of the situation and helped expedite the review processes.

Remote monitoring and electronic documentation systems were deployed so site oversight could continue even when in-person visits were restricted. Contingency plans were developed iteratively and adapted as the pandemic situation evolved week by week.

Import logistics for the investigational product were coordinated with customs authorities, and the cold-chain process for biological specimens was mapped and verified before any samples were collected. Pakistan's research community rose to the challenge, navigating unprecedented operational and scientific complexities to support a timely response to the global emergency.

The Result

The trial expanded into Pakistan successfully. New participants were enrolled, contributing meaningfully to the sponsor's global development program and helping maintain the timelines that might otherwise have been lost. This project experience didn't just solve a recruitment problem; it demonstrated that Pakistan could handle some of the most demanding conditions in clinical research.

When the work becomes complex, Pakistan has the capability, capacity, and maturity to handle it.

Case Study 2:
Advancing Infectious Disease Diagnostics in Real-World Settings

The Context

Tuberculosis, dengue, and hepatitis are not abstractions in Pakistan. They show up in clinics every day, in patients who have often waited too long for a diagnosis because the tools to detect their condition quickly and reliably simply were not available or were not easy enough to use where they were needed most.

Over the course of three separate studies, that gap became

the focus. Each project tackled the problem from a different angle, with a different technology. Together, they add up to something more than three data sets; they tell a story about what medical diagnostic innovation actually looks like when it meets the real world.

Study One: Seeing TB Differently

The first study evaluated an imaging-based camera system designed to support the diagnosis of tuberculosis. Rather than relying solely on traditional lab methods, this technology offered a way to visually assess patients, capturing information that could be reviewed, documented, and compared over time. The research team had to design workflows that fit around clinical reality. Training was structured so that investigators understood not just how to operate the device, but how to ensure the data it captured was consistent and reliable across every patient encounter. Quality oversight ran in parallel throughout, so that any variation could be identified and corrected early. (Zaidi et al. 2018)

Study Two: Rapid Diagnostic Testing for Dengue

Dengue does not give clinicians much time. When a suspected case walks into a hospital, the pressure to confirm or rule out the diagnosis quickly is real because treatment decisions follow immediately, and the window matters. That urgency is exactly what made this study worth doing, and exactly what made it demanding to run.

Rapid diagnostic testing was evaluated across hospital sites in Pakistan to assess its ability to detect infection at different stages — from early antigen detection through to antibody response. The question was whether it worked in busy wards, with high patient volumes, varied clinical workflows, and staff making decisions under pressure. Standardizing how the test was administered, how results were interpreted, and how findings were recorded across multiple sites was one of the study's core challenges. It was also one of its core achievements.

Study Three: Putting Hepatitis Testing in Participants' Hands

The third study was different from the first two. A hepatitis diagnostic device was designed to be used not by clinicians, but by lay users: ordinary people following written instructions without specialist training. That changed the question. The study was not only asking whether the device could produce a result. It was asking whether people could use it correctly on their own. Could they follow the instructions? Did they understand each step? Where did they hesitate, misread, or need to start again? (Mazzilli et al. 2024)

A study observer monitored each participant as they worked through the process, documenting not only whether the test was completed correctly but also how the user interacted with the device. That observational data made the usability evidence credible and helped show whether the device was ready for real-world use.

Three technologies. Three diseases. Three very different research questions — connected by a single principle: diagnostic innovation only matters if it works for the people and settings it is meant to serve.

Case Study 3: Pakistan as a Global Centralized Management & Operations Hub

The Context

Pakistan has spent years building a clinical research infrastructure that the global market is now fully appreciating: highly trained investigators, experienced research professionals, and a regulatory environment that has matured steadily. An unforeseen evolution of this growth is Pakistan's emergence as a centralized hub from which international clinical trials can be strategically managed, coordinated, and kept on track.

The Shift Toward Centralized Management and Hybrid Operations

For many years, clinical trial management and monitoring were heavily siloed, relying almost entirely on localized, fragmented teams and frequent, costly physical site visits. While local presence remains essential for direct source document verification and physical site audits, the evolution of decentralized systems, electronic documentation, and risk-based methodologies has transformed the operational model.

With the right digital infrastructure and highly trained personnel, complex global trials can now be driven by a centralized project management hub. This hub provides continuous oversight, harmonizes data, and directs local field assets, delivering high-quality, efficient trial execution while maintaining strict compliance with ICH-GCP and sponsor expectations. Pakistan has developed the talent pool, systems, and operational discipline needed to anchor this modern, hybrid model.

South America Sites: End-to-End Operational Oversight from Pakistan

In one engagement, a sponsor required comprehensive management and operational support for a clinical study being conducted in South America. Pakistan's clinical

research team stepped in as the Centralized Project Management and Operational Hub, directing the trial's life cycle from thousands of miles away.

The scope extended far beyond traditional administrative tasks. Acting on behalf of the sponsor, the Pakistan-based hub coordinated the development of essential study documents, mapped out ethics committee strategies, and meticulously prepared site initiation dossiers for local execution. While local field CRAs performed necessary on-site data verification to comply with regional data privacy laws, the team in Pakistan managed the centralized quality control, Electronic Data Capture (EDC) oversight, and continuous trial metrics review.

From Pakistan, the team led the centralized coordination of site close-out activities, laboratory logistics, document translations, customs clearance support, sample shipment tracking, trial insurance procurement, and Trial Master File (TMF) archiving. Managing these complex workstreams required continuous coordination across countries, distinct operational teams, and shifting time zones. Study progress and data quality were maintained seamlessly, proving that while physical site alignment was maintained locally, the operational brain of the study lived in Pakistan.

MENA: Operational Support Across Borders

The second engagement highlighted the hub's ability to manage complex, multi-border regulatory and stakeholder dynamics. A UK-based sponsor executing a clinical study in MENA required an operational anchor to bridge the gaps. (Metrics Research 2024)

Pakistan's clinical project management team took on the role of central coordinator. Working closely with local MENA partners and investigators, the Pakistani hub facilitated the preparation of ethical and regulatory submissions, drafted standard operating pathways, and identified viable investigative sites.

The team successfully synchronized communication and milestones across three different countries with stakeholders who had never worked together before. The study moved forward smoothly because a central team understood both the global science and the local operational realities, building a compliant foundation before the first patient was ever enrolled.

What This Represents

Two studies. Two different continents. Two entirely different sets of challenges. What connects them is a refusal to be limited by geography.

Pakistan's clinical research capability is no longer defined by its physical borders. By acting as a sophisticated, centralized hub that aligns seamlessly with local field teams worldwide, Pakistan is proving it can deliver the rigorous quality, cross-border coordination, and operational discipline required by today's global clinical trials. (Shabbir 2024)

Pakistan is no longer just participating in global clinical research; it is helping shape how global clinical research is delivered.

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Risk It? No Thanks!
Mastering Risk Identification & Mitigation in Clinical Trials

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Introduction

Pakistan is rapidly becoming a leading destination for global clinical trials in 2026. With a large treatment-naïve population and a unique "Triple Burden" of infectious diseases, non-communicable diseases, and nutritional deficiencies, the country offers exceptional research value (Raheem et al. 2024; Basit et al. 2019; Haq et al. 2025). Over 5,000 clinical research projects have been registered from Pakistan up to 2025, reflecting significant growth in the field (National Library of Medicine 2025). However, modern trials are far more complex than before, making traditional quality management methods difficult to sustain. Risk management is now central to ensuring patient safety, data integrity, and efficient use of resources (FDA 2013).

Regulators are also driving change. The finalized ICH E6(R3) guidelines call for a shift toward a Quality by Design (QbD) approach, prioritizing proactive risk management over reactive fixes (ICH 2025; ICH 2021). The long-standing practice of 100% Source Data Verification (SDV), while thorough in theory, is resource-intensive and still misses systemic errors (TransCelerate 2013). Risk-Based Monitoring (RBM) has emerged as the smarter alternative, focusing efforts where they matter most (FDA 2013).

Risk vs. Problem

A fundamental error in trial management is confusing risks with problems.

- **Defining Risk:** Risk is defined as "the effect of uncertainty on objectives" (DDR 2021). It is an expression of the likelihood that a potential event may happen and the impact it may have on trial integrity or patient safety.
- **Defining Problem:** A problem is a risk that has already materialized (DDR 2021).

When research teams fail to differentiate the two, they operate in a purely reactive state—similar to "putting out fires" rather than preventing them. This leads to heavy reliance on Corrective and Preventive Actions (CAPAs) rather than proactive trial design.

Clinical Example:

- **Risk:** Due to complex inclusion criteria, a protocol deviation regarding patient eligibility may occur.
- **Problem:** An ineligible patient was randomized into the trial.

The Risk-Based Approach (RBA)

A Risk-Based Approach (RBA) is a strategic methodology that tailors the level of oversight and monitoring to the specific risk profile of a trial (FDA 2013). It relies heavily on Centralized Monitoring, using data analytics to guide targeted on-site oversight (TransCelerate 2013).

Core Principles of RBA:

- **Proportionality:** Oversight efforts should match the level of risk (ICH 2025).
- Systematic Thinking: Evaluating the trial protocol holistically (ICH 2025).
- **Continuous Evaluation:** Recognizing that risk profiles change over time (ICH 2025).

The Risk Management Lifecycle follows a continuous loop:

Identify → Assess → Mitigate → Monitor → Review

Figure 1: Risk Managememt Cycle

Identifying Risks in the Clinical Trial Process

Risk identification must occur proactively across the entire trial lifecycle, starting during protocol development (ICH 2021). Risks can be categorized into:

1. **System-level risks:** Electronic data capture failures (Harris et al. 2019).
2. **Facility-level risks:** Equipment calibration and infrastructural fragility (Alemayehu, Mitchell, and Nikles 2018).
3. **Trial-level risks:** Investigational product handling or inadequate blinding methodologies (Siddique, Zafar, and Irfan 2022).

Tools for Risk Identification: The most standard tool is the Risk Assessment and Categorization Tool (RACT), which helps sponsors and trial managers systematically map out potential vulnerabilities before the trial begins (TransCelerate 2013).

The Risk Matrix

A Risk Matrix is a visual and mathematical tool used to assess and categorize risks based on two primary dimensions: Likelihood (probability of occurrence) and Impact (severity of consequence on data integrity, participant safety, or regulatory compliance) (DDR 2021). The risk can be quantified using the fundamental equation outlined in the ICH E6(R3) context (ICH 2025):

Risk Criticality = Probability × Severity of Impact

By plotting these dimensions, risks are assigned a criticality score, typically categorized into Low, Medium, High, or Critical levels (TransCelerate 2013).

			Impact				
			Very low	Low	Medium	High	Very high
			1	2	3	4	5
Probability	Very low	1	1	2	3	4	5
	Low	2	2	4	6	8	10
	Medium	3	3	6	9	12	15
	High	4	4	8	12	16	20
	Very high	5	5	10	15	20	25
			1		2	3	4
			Low		Moderate	Significant	Severe
			Criticality				

Table 1: The Standard Clinical Trial Risk Matrix (Wawra-Hehenberger et al. 2025)

SCORING GUIDE — RISK RATING INTERPRETATION AND REQUIRED ACTIONS		
9	**CRITICAL**	Immediate escalation to sponsor/CRO medical monitor required. Study halt or urgent CAPA warranted. Regulatory notification likely required.
6	**HIGH**	Priority risk. A mitigation plan required before or at study initiation. Review at every monitoring visit. Assign a named owner.
3–4	**MEDIUM**	Managed risk. Mitigation action required. Monitor per standard schedule. Review at each site visit or central monitoring cycle.
1–2	**LOW**	Acceptable risk. Document and monitor. No immediate action is required, but it should be reviewed at protocol deviation review meetings.

Example: If an Investigational Product (IP) has strict temperature requirements, a site power outage has a "Moderate Likelihood" but a "High Impact" on patient safety and trial data (FDA 2013). This plots as a "High Risk," requiring immediate preventive measures such as continuous temperature logging and backup generators (FDA 2013).

Using the matrix ensures prioritization (FDA 2013). Not all risks need equal attention; resources are strictly allocated to High and Critical risks (FDA 2013).

Developing Mitigation Strategies

A strong mitigation plan maps specific actions to identified risks. Responses generally fall into four strategic categories:

- **Mitigate:** Reduce the impact/likelihood.
- **Tolerate:** Accept minor risks, such as local public holiday delays, due to acceptable exposure.
- **Transfer:** Shift financial risks using comprehensive clinical trial insurance.
- **Terminate:** Avoid the risk entirely, such as abandoning outdated paper forms for eConsent.

Mitigation Elements:

- **Preventive Actions:** Steps taken before a risk materializes (ICH 2025).
- **Corrective Actions:** Steps taken if risk indicators are triggered (ICH 2025).
- **Key Risk Indicators (KRIs):** Measurable metrics (e.g., >10% missing data) that trigger early warnings (TransCelerate 2013).
- **Assigned Ownership:** A designated individual accountable for monitoring the risk (ICH 2025).

CAPA, in the context of risk management, is used primarily when a risk has bypassed preventive measures and materialized into an actual problem. Documenting these elements in a centralized Risk Management Plan (RMP) is a regulatory expectation under ICH guidelines (ICH 2025).

Monitoring and Reviewing Risks

Risk management is an iterative, living process; it is not a one-time exercise (ICH 2025). Risks must be reviewed continuously during trial oversight meetings, site monitoring visits, and Trial Master File (TMF) reviews (ICH 2025).

Clear escalation pathways must be established so that when a KRI threshold is breached, the risk is escalated to trial leadership before it becomes a serious problem (TransCelerate 2013). Centralized Statistical Monitoring (CSM) plays a critical role here, using statistical tools to identify unusual data patterns across sites (FDA 2013).

Translating Knowledge into Behavior Change

Moving from awareness to behavior requires a cultural shift towards a "Just Culture," where proactive reporting of near-misses is actively praised and encouraged by leadership (ICH 2021).

Risk-aware research professionals actively question protocol feasibility, engage with the RACT early, and utilize KRI dashboards rather than blindly performing 100% SDV (TransCelerate 2013).

Reflection for the Reader: Self-Assessment Checklist

Use this checklist to benchmark your current practice. For each statement, reflect honestly on whether this is something you do consistently. Identify two or three gaps and commit to addressing them in your next trial.

S. No.	Practice Statement	Yes	No
	Risk Planning		
1	I proactively identify potential risks at study start-up, not only after a deviation occurs.		
2	I can distinguish between a risk (potential future event) and a problem (a risk that has materialized).		
3	I contribute to or review the Risk Management Plan (RMP) for each trial I work on.		

S. No.	Practice Statement	Yes	No
	Mitigation & Documentation		
4	Each identified risk in my trials has a named owner and a documented mitigation action.		
5	I understand the difference between a preventive action and a corrective action (CAPA).		
6	I know which Key Risk Indicators (KRIs) are defined for my study and what the trigger thresholds (QTLs) are.		
7	I document risk-related observations during monitoring visits, not only protocol deviations.		
	Monitoring & Escalation		
8	I review KRI dashboards or centralized monitoring outputs between site visits.		
9	I know my trial's escalation pathway — who to contact when a KRI threshold is breached.		
10	Risk review is a standing agenda item in my trial team meetings.		
11	I flag emerging signals to the sponsor or CRO before they become findings or inspection observations.		
	Behavior & Mindset		
12	I ask 'What could go wrong here?' when reviewing new protocols or amendments.		
13	I treat a near-miss or triggered KRI as valuable intelligence, not just a non-event.		
14	I contribute risk knowledge from previous trials to new study planning discussions.		
15	I can name one concrete action I will take in my next trial to strengthen my risk-based practice.		

Scoring guide:

13–15: Consistent. Strong risk-based practice

8–12: Developing

Below 8: Priority areas identified for professional development

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Digital Transformation in Pakistan's Clinical Trials Market: Opportunities, Infrastructure Readiness, & Regulatory Challenges

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Introduction

There is rapid digitalization of clinical trials due to advantages such as data accuracy, reliability, transparency, ready availability for analysis, and global compliance. This digitalization is further augmented by the necessity and advancements in technology such as artificial intelligence (AI), cloud computing, EDC, and decentralized clinical trials. This represents an opportunity for Pakistan, a lower-middle-income country that has more than 240 million people and rising cases of non-communicable diseases. With a high number of treatment-naïve patients, increasing investment from the pharmaceutical industry in carrying out clinical research, and a changing regulatory landscape, there is potential for Pakistan to become a digital hub for clinical trials. To realize this, some of the issues that have been observed in digital health in Pakistan have to be addressed, including infrastructural weaknesses, gaps in the skillsets of the workforce, and regulatory issues. In this review article, the opportunities for digital transformation in the field of clinical trials in Pakistan are explored, along with infrastructure and regulatory issues that need consideration.

The Opportunity Landscape

Pakistan has a fascinating landscape for clinical trials, offering a lot of potential. In addition, the country has some of the highest disease burdens in therapeutic areas like diabetes, cardiovascular disease, breast cancer, tuberculosis, and hepatitis B and C and provides sponsors access to patient populations that are larger and more diverse, which are becoming increasingly hard to recruit in saturated Western markets (Ahmed, Aamir, and Williams 2023).

With increasing mobile connectivity and expanding urban health infrastructure, Pakistan possesses considerable potential for adopting digital life sciences technologies, including eClinical solutions, AI-powered trial design, and cloud-based data management, with the clinical trials segment having the highest market share in the digital life sciences ecosystem (BioSpace 2025). This can broaden the reach of clinical research beyond the tertiary care hospitals in Karachi, Lahore, and Islamabad.

Infrastructure Readiness: A Mixed Picture

Although Pakistan's digital health infrastructure has improved in recent years, readiness for digitally enabled clinical trials remains uneven. Only 27% of analyzed digital health projects utilized cloud-based storage, while most relied on local servers, limiting scalability, real-time data access, and auditability required by modern clinical trial management systems (Kazi et al. 2020).

In addition, the internet connectivity and power supply issues are significant concerns in rural and remote regions of Pakistan, and this adds to the difficulties in maintaining a consistent use of digital platforms (Frontiers in Digital Health 2026). Several public health facilities do not have interoperable health information systems, posing challenges for integration at the trial sites and making multi-center data aggregation more complex. There is also a stark disparity between rural and urban hospitals: District and Sub-district hospitals are still mostly paper-based, whereas tertiary academic medical centers in urban areas are increasingly implementing EMRs and data management systems, making it difficult to implement nationwide or truly decentralized digital trials in Pakistan.

There are some positive signs of improvement, however, the increasing urbanization of mobile broadband networks offers the opportunity for patient-facing technologies such as electronic patient-reported outcomes (ePRO) and for telemedicine-based trial monitoring. Pakistan's government-backed National Economic Transformation Plan (Uraan Pakistan, 2024–29) explicitly calls for digital modernization of critical economic sectors, which would act as a policy tailwind for health digitization (Government of Pakistan 2024).

Regulatory Challenges and Evolving Frameworks

Drug Regulatory Authority of Pakistan (DRAP), under the umbrella of Bio Study Rules 2017 and the overall jurisdiction of the Drugs Act, 1976, is the central regulatory body responsible for overseeing clinical trials. The DRAP has recently revised the Guidelines on Conduct of Clinical Studies to solicit public comments on updates to the Guidelines from various aspects including approval of clinical studies, informed consent, adverse events reporting,

sponsor and investigator roles, etc. which is a commendable initiative to bring the framework in line with international good clinical practice (GCP) standards (Drug Regulatory Authority of Pakistan [DRAP] 2026).

In addition, DRAP extended its Industry E-Reporting System for Adverse Drug Reactions to all DRAP registration holders following a successful pilot, and implementation of electronic submission of reports was planned from November 2024 (DRAP 2024b), a step towards regulatory modernization. Furthermore, in July 2025, DRAP formally opened a Digital System for Licensing and Registration of Medical Devices, where electronic submission of reports will be required with the introduction of the system, which is another step towards regulatory digitization (DRAP 2025), but the speed of digitization of the regulatory architecture at trial execution in modern and digital settings remains untapped.

The majority of funding sources for clinical trials in Pakistan come from international pharmaceutical companies and health organizations, not from domestic public funding, which means Pakistan cannot have an independent stance in setting research priorities that are relevant to its disease burden. Insufficient regulatory attention towards this matter is also one of the contributing barriers to the growth of digital clinical research in Pakistan, along with chronic underfunding and a shortage of trained research professionals (Mumtaz et al. 2024). The reforms that are prioritized include streamlining ethical approval procedures, building a network of investigators trained in Good Clinical Practice, and creating digital portals that enable electronic submission of documents to regulators.

The Path Forward: Strategic Imperatives

It is important to understand that Pakistan has the potential to become a digitally capable clinical trial market and this can be achieved through efforts on three fronts. **First,** infrastructure investment needs to be scaled up, particularly for the deployment of interoperable health information systems in public hospitals, & the extension of broadband infrastructure to semi-urban and rural areas; and the development of cloud-based data management facilities that conform with international standards of the trials. The potential public-private partnerships available in the country can provide a practical system to address this divide. **Second,** the modernization of regulation needs to go beyond policy modifications to the full submission, review and approval processes, including digital systems, that can meet the turnaround times of sponsors from the rest of the world (IQVIA 2024). While these e-reporting initiatives by DRAP are a start, they don't cover the whole gamut of trial supervision processes, and the regulatory process needs to be fully digitized in order to stay competitive with other research markets such as India and Bangladesh.

Third, Pakistan needs to invest in its human resources. More specifically, the need for a network of CRCs, DMs, and GCP-certified investigators is critical to support multi-site, digitally integrated trials. A variety of stakeholders, including institutions, pharmaceutical associations, & international health organizations, can contribute to the development of this workforce. Cultural & linguistic factors should also be taken into account when designing digital patient engagement tools, to ensure that ePRO instruments and telemedicine platforms are accessible to the wide and multilingual patient population in Pakistan.

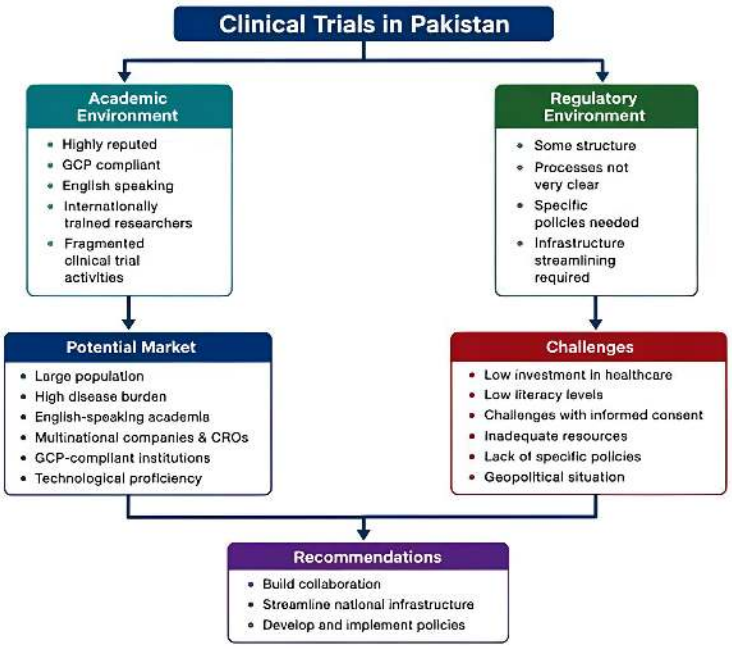

Figure 1. Clinical Trials in Pakistan: Opportunities and Challenges (adapted from Irumnaz & Nair, 2014).

Conclusion

Digital transformation is a real possibility for Pakistan to take the clinical trials industry from a bystander to a significant contributor to global pharmaceutical research. A sound basis is provided by the country's population scale, disease diversity, and increasing regulatory commitment. However, the road to change is not smooth: the digital infrastructure is not uniformly distributed, health information systems are not fully integrated, regulations are not yet aligned, and resources are scarce. Investment in infrastructure, modernization of the regulation, and human capacity building are the strategic imperatives that are clear. With the coordinated use of time and effort, Pakistan's policymakers, regulatory bodies, and research institutions can use the digital revolution in clinical trials to enhance the research output as well as the health of the Pakistani people.

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AI-Enabled Clinical Trial Operations in Pakistan

Juhainah Mubarak, Central Clinical Data Coordinator, DM Clinical Research

Pakistan's AI-in-Healthcare Ecosystem: Evidence Review

Artificial intelligence (AI) has gained global prominence and is increasingly recognized as a cornerstone of the Fourth Industrial Revolution. (Abid et al. 2019). Artificial intelligence has evolved from supporting healthcare delivery and clinical decision-making to becoming an increasingly important component of clinical research. Advances in machine learning, predictive analytics, and digital health technologies are enabling AI applications across the clinical trial lifecycle, including protocol design, patient recruitment, data management, monitoring, and trial optimization, reflecting a broader shift toward more data-driven and technology-enabled clinical research. (Rajpurkar et al. 2022; Umer, Khan, and Ayaz 2023).

Pakistan is at an early but steadily advancing stage of AI integration in healthcare, specifically the clinical research domain. While the direct application of AI to clinical trial operations remains limited and largely undocumented, the broader AI-healthcare ecosystem is gaining momentum through national digital health initiatives, academic research, and increasing institutional interest in data-driven healthcare. The National Digital Health Framework (NDHF) 2022–2030 provides a strategic foundation for digital transformation through the promotion of electronic health records, health information exchange systems, and emerging AI technologies (Government of Pakistan 2022). Studies have also reported positive perceptions of AI among healthcare professionals, particularly regarding its potential to improve clinical decision-making, diagnostics, patient safety, and healthcare efficiency, despite ongoing challenges related to infrastructure, governance, regulation, and workforce readiness (Yousif et al. 2024). Collectively, these developments provide an important foundation for future AI-enabled clinical research in Pakistan.

AI Applications in Clinical Trials

Pakistan is increasingly recognized as a potential destination for multinational clinical research due to its large and diverse population, availability of treatment-naïve patients, and cost-efficient research environment. The country's clinical research ecosystem is supported by internationally accredited healthcare institutions, WHO-inspected laboratories, JCI- and ISO-certified institutions, and an evolving regulatory framework overseen by the Drug Regulatory Authority of Pakistan (DRAP). These factors, combined with an experienced healthcare workforce and growing research capacity, provide a foundation for expanding participation in global clinical trials (IQVIA).

As clinical trials increasingly evolve toward data-driven, technology-enabled models, the integration of artificial intelligence represents one of the most significant trends shaping the future of clinical research. As illustrated in Figure 1a, AI has the potential to enhance multiple stages of the clinical trial lifecycle, from protocol design and patient recruitment to data management, monitoring, and predictive analytics. AI-powered tools can optimize study protocols, identify eligible participants more efficiently through electronic health records and clinical data, automate data processing, support risk-based monitoring, and predict potential trial challenges before they occur. Globally, these technologies are increasingly being used to enhance trial efficiency, safety monitoring, and overall study performance.

Regulatory Challenges and Evolving Frameworks

Drug Regulatory Authority of Pakistan (DRAP), under the umbrella of Bio Study Rules 2017 and the overall jurisdiction of the Drugs Act, 1976, is the central regulatory body responsible for overseeing clinical trials. The DRAP has recently revised the Guidelines on Conduct of Clinical Studies to solicit public comments on updates to the Guidelines from various aspects including approval of clinical studies, informed consent, adverse events reporting,

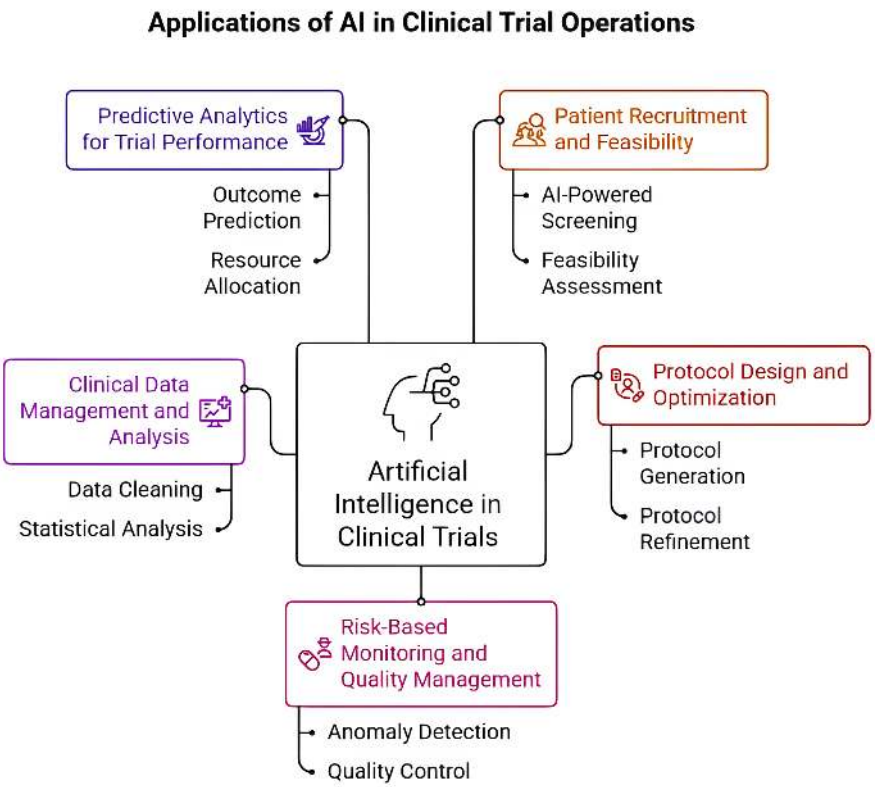

Figure 1a: Applications of AI in Clinical Trial Operations

Global AI-Powered Clinical Trial Platforms: Potential opportunity for Pakistan

The adoption of globally established AI-enabled clinical trial platforms, as mentioned in Table 2 present a significant opportunity for Pakistan's clinical research sector. These technologies have demonstrated value in protocol optimization, clinical data analytics, real-world evidence generation, and risk-based trial management. Their integration into Pakistan's evolving research ecosystem could help address longstanding operational challenges, enhance trial efficiency, and position the country as a more attractive destination for international clinical research and AI-enabled clinical trials.

Table 1: List of AI enabled software used in Clinical Trials globally

Software	Company	Primary AI Application
Medidata Rave & Acorn AI	Medidata	Trial design, synthetic controls, protocol optimization, predictive analytics
IQVIA AI Suite	IQVIA	Recruitment, site feasibility, RWE analytics, trial optimization
Veeva Vault Clinical Platform	Veeva Systems	Unified cloud platform for clinical operations, including CTMS, EDC, eTMF, RTSM, and SiteVault. Veeva AI Agents — built on LLMs
Deep 6 AI (now Tempus)	Tempus AI	AI and NLP platform that mines structured and unstructured EHR data, including clinical notes, lab values, imaging reports, and pathology, to match real patients to trial eligibility criteria
Oracle Health Sciences (Clinical One)	Oracle Corporation	Unifies EDC and RTSM in a single platform with real-time subject data access, automated data validations, AI-powered enrolment forecasting, and zero-downtime mid-study updates

Pakistan Clinical Research- AI Initiatives

Although documented examples of AI-enabled clinical trial operations in Pakistan remain limited, several institutions have begun establishing the foundations necessary for future adoption. As shown in Table 1, current initiatives are concentrated in digital health innovation, clinical decision support, AI-enabled healthcare research, workforce development, and research capacity building.

Academic institutions such as Aga Khan University, King Edward Medical University, Shifa Tameer-e-Millat University- Shifa Centre of Excellence, and LUMHS are promoting AI research and innovation, while organizations such as NUMS are investing in clinical research training. Together, these efforts suggest that Pakistan's AI ecosystem is currently evolving through healthcare innovation and research capacity building rather than direct deployment of AI in clinical trial operations, providing a foundation for future integration of AI-driven research technologies.

Table 2: Pakistan's Clinical Research - AI initiatives

Area	Project	Lead Organization(s) / Team
Clinical decision support & digital health	The "Awaaz-e-Sehat" project developed an AI-powered system that converts Urdu speech into electronic medical records and provides decision support in maternal healthcare.	Researchers working in Pakistan's maternal health ecosystem
AI Diagnostics, Digital Health, and Clinical Decision Support	AI-powered cough analysis for tuberculosis diagnosis and machine-learning models for maternal and child health have ongoing work in this area.	Agha Khan University
Medical research and AI innovation	National undergraduate and academic research conferences increasingly include AI-healthcare research tracks and AI-integrated medical research presentations.	King Edward Medical University
Clinical Research Capacity Building and AI Awareness	Symposium titled "Clinical Trials in the Era of AI"	Shifa Tameer-e-Millat University / Shifa Centre of Excellence- SCOPE
Clinical Research Program – bridging Academia and Industry	Certificate and Diploma in Clinical Research (2026); workforce development and research capacity building	NUMS – National University of Medical Sciences
Clinical Research Infrastructure and Translational Research	Supporting clinical research, trial sites, and national/international collaborations	LUMHS Medical Research Centre
AI Research, Machine Learning, Big Data, and Healthcare AI Innovation	Supports AI research in healthcare, data science, medical imaging, and digital health innovation	National Center of Artificial Intelligence (NCAI)
AI Clinical Documentation and Physician Support	AI physician assistant (HAMI) initially deployed in Pakistan for clinical documentation and decision support	Boston Health AI
AI-assisted health research	Xylexa assists Radiologists and Caregivers with accurate, timely & cost-effective medical image interpretation.	Xylexa

Readiness and Challenges for Integrating AI into Pakistan's Clinical Trial Ecosystem

Pakistan has enhanced its clinical research infrastructure through DRAP-approved trial sites, accredited hospitals, and established ethical oversight (DRAP 2025; Sherin 2023). However, AI adoption is hindered by fragmented health information systems, limited interoperability of electronic health records, workforce training needs, data standardization, and evolving governance for health data and AI (Government of Pakistan 2022; Yousif et al. 2024). Despite interest in AI, documented applications in clinical trials are sparse, with few examples of AI-driven patient recruitment, site selection, and trial management. Bridging these gaps will require targeted investment, supportive policies, and pilot initiatives.

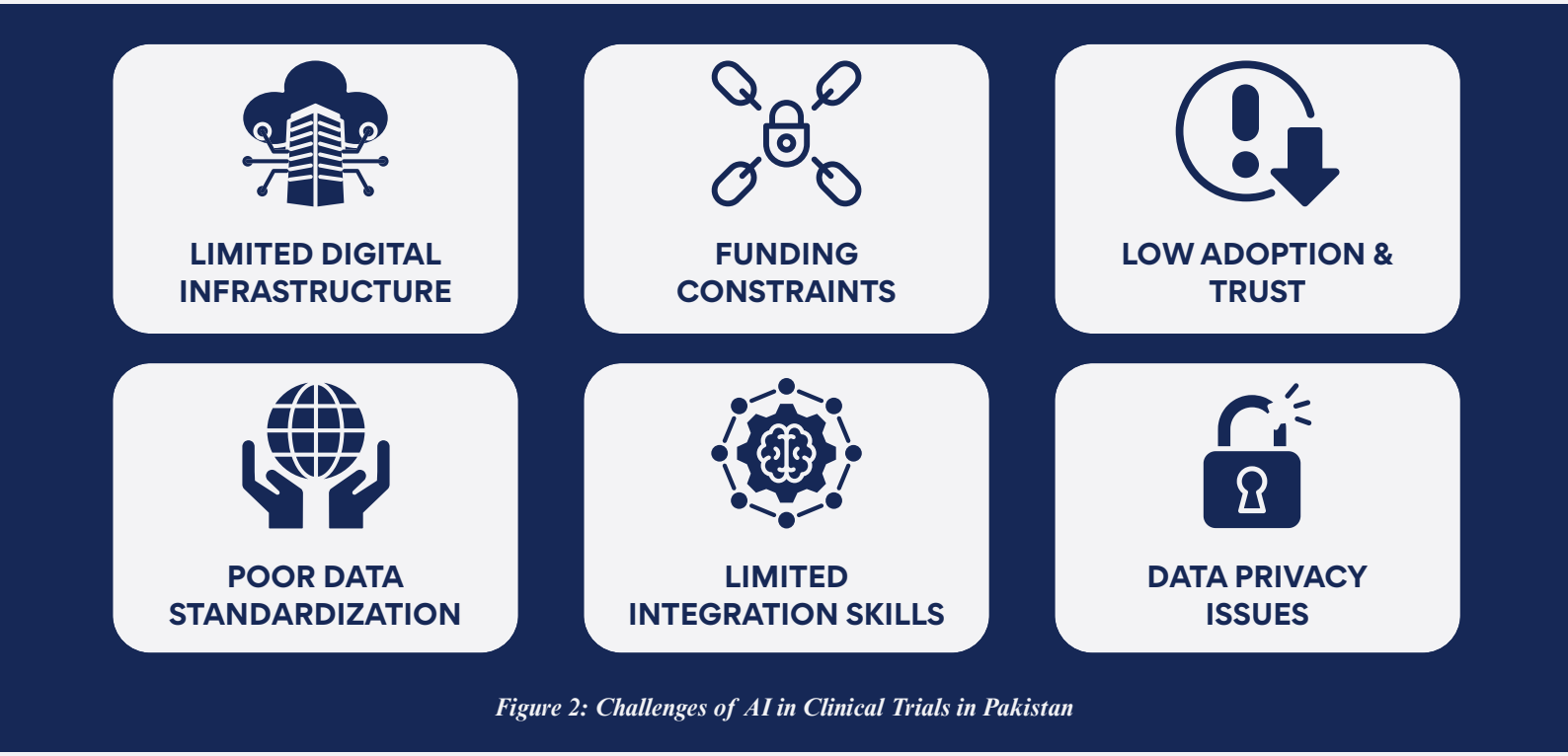

Figure 2: Challenges of AI in Clinical Trials in Pakistan

Roadmap: AI-Enabling Clinical Research in Pakistan

AI presents opportunities to enhance clinical research in resource-limited settings like Pakistan. A strategic roadmap should focus on improving digital health infrastructure, increasing electronic health record use, developing skilled professionals, and promoting collaboration among academic institutions, healthcare providers, and technology partners.

Initiatives at Aga Khan University and training programs at NUMS are boosting national digital capacity. Adopting AI technologies for patient recruitment, data analytics, and trial management can improve research efficiency and participation in multinational studies. Achieving this potential requires ongoing investment in infrastructure and workforce development. (World Health Organization 2021; Mustafa et al. 2026).

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Advancing National Clinical Trial Capacity: Key Initiatives by the Aga Khan University WHO Collaborating Centre

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As a WHO Collaborating Centre, CTU AKU is committed to building capacities across the clinical trials ecosystem using global best-practice guidance. In pursuit of this mission, CTU has undertaken several impactful capacity-building activities.

Symposium on "Risk-Based Strategies across Clinical Trials Ecosystem"

The Clinical Trials Unit, Aga Khan University, in collaboration with the World Health Organization and the Drug Regulatory Authority of Pakistan, hosted a two-day symposium on Risk-Based Strategies Across the Clinical Trial Ecosystem. The event brought together national and international experts to strengthen the understanding and practical implementation of risk-based approaches across the clinical trial lifecycle — encompassing risk assessment, risk management planning, quality management systems, and Risk-Based Monitoring (RBM).

Day 1 featured distinguished speakers, including WHO representatives, ethical and regulatory voices from across Pakistan, and two international virtual speakers from IQVIA (Asia Pacific) and ProMedix CRO (Turkey). Topics covered included risk-based regulatory strategies, RBM models and tools, ICH E6(R3) alignment, site-level risk management, and data integrity, with real-world case discussions grounding sessions in practice. The event drew both in-person and online participants nationally and internationally.

Day 2 translated knowledge into action through an intensive hands-on workshop. Participants from institutions across the country worked collaboratively to identify, assess, mitigate, and monitor clinical trial risks, culminating in the development of site-level Risk-Based Monitoring Plans. Facilitated by the CTU team alongside clinical trial experts from across Pakistan, the workshop was met with strong engagement, reflecting both the relevance of the subject and participants' commitment to advancing risk-based practice in their institutions.

IOP Team Visit to CTU

The Institute of Psychiatry (IOP), a collaborator on the Centre of Impact grant led by Principal Investigator Dr. Zainab Samad, visited the Clinical Trials Unit on 3–4 February 2026 as part of the grant's research capacity-strengthening component. The IOP team, planning to initiate a drug trial on Diabetes Mellitus and mental health in Rawalpindi/Islamabad, engaged in comprehensive sessions covering CTU's operational framework, startup and approval processes (including NBC and DRAP), execution of agreements, trial initiation requirements, and the roles of pharmacy and laboratory services. A guided facility tour and structured walkthrough of the Hepatitis C Phase III study provided practical exposure to participant workflow, informed consent, randomization, source documentation, data management, and GCP-compliant practices.

On Day 2, sessions focused on patient screening, enrolment and retention strategies, data management, and source documentation. Dedicated discussions covered CTU Pharmacy operations including the Investigational Medicinal Product (IMP) lifecycle, cold-chain management, sterile compounding, and secure documentation, as well as CTU Laboratory workflows encompassing phlebotomy, sample processing, centrifugation, storage, and shipment. The visit equipped the IOP team with practical knowledge and operational insights needed to effectively initiate and conduct their upcoming clinical trial.

Virtual Training on Hepatitis-B & C Testing in Key Populations in Pakistan

A virtual training was conducted on 10 February 2026, organized by CTU AKU in collaboration with UNDP, targeting CBO outreach workers, supervisors, and field staff. The training aimed to strengthen frontline testing capacity in key populations, support equitable access to early diagnosis and linkage to care, and provide a scalable capacity-building model applicable to similar low- and middle-income settings contributing to earlier detection, reduced transmission, and progress toward regional elimination targets.

Prof. Faisal Mehmood (Head of Infectious Diseases, AKU) delivered an overview of Hepatitis-B, Hepatitis-C, and

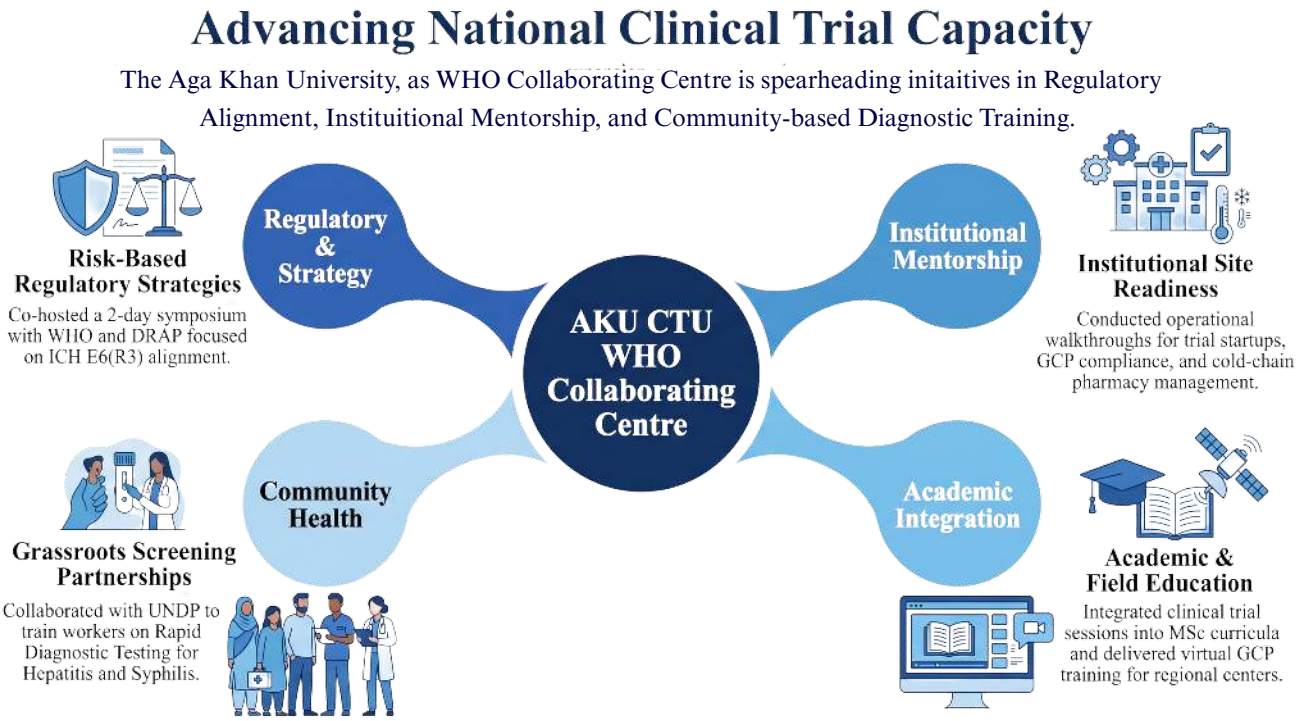
Syphilis, while Prof. Saeed S. Hamid (Director, CTU; Professor and Consultant Gastroenterologist, AKU) presented on the importance of Hepatitis-B and Hepatitis-C screening in key populations. The CTU Laboratory team demonstrated the use and result interpretation of Rapid Diagnostic Testing (RDT) kits for Hepatitis B and C.

IOP Team Visit to CTU

The CTU conducted a virtual GCP refresher training for the Matiari Research Centre field team on 12 February 2026. The training supported WHO's agenda by strengthening ethical and regulatory compliance at the site level, improving data quality and reliability, and enhancing trial readiness and audit preparedness across satellite centres. This initiative promotes harmonized research practices and contributes to building a collaborative and resilient clinical research network across sites

Session in PATCT Course 2026

The Clinical Trials Unit was invited to deliver a session in the "Introduction to Pharmacoepidemiology & Advanced Topics in Clinical Trials (PATCT)" course for the MSc Epidemiology and Biostatistics (Semester III) program. Conducted on 27 March 2026, the session covered Good Clinical Practice, ethical and regulatory compliance, practical aspects of trial conduct, data management and documentation, and investigational product management. The session aimed to enhance students' understanding of clinical trial operations and strengthen their practical knowledge for conducting research in compliance with international standards.



Regional Clinical Research Scenario: Current Status, Challenges, and Future Opportunities

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Introduction

Clinical trials are essential for the development and approval of new drugs for medical use (Bhatt and Mehta 2016). These trials provide invaluable insights into the efficacy, safety, and appropriate dosing of potential pharmaceuticals, allowing healthcare professionals to provide patients with effective treatment options.

The clinical trials market is valued at USD 131.8 billion in 2026 and is projected to reach USD 200.9 billion by 2036, expanding at a CAGR of 4.3% during the forecast period. Growth reflects the increasing complexity of drug development and a steady rise in research activity across pharmaceuticals, biotechnology, and medical devices. Sponsors continue to scale trial volumes as pipelines move toward targeted therapies, biologics, and advanced treatment approaches that require extensive clinical validation (Future Market Insights 2025).

Demand is shaped by the growing burden of chronic diseases, oncology indications, and rare disorders that require long-term studies and multi-phase evaluations. Pharmaceutical companies depend on structured trial programs to meet regulatory expectations while managing the development timelines and investment risks. Biotechnology firms add strong momentum as innovation accelerates in gene therapies, cell-based treatments, and personalized medicine. Medical device manufacturers also contribute through trials focused on safety assessment, performance validation, and post-approval studies (Bhatt and Mehta 2016).

Global and Regional Clinical Research Landscape

Regional demand remains concentrated in North America and Europe, supported by mature regulatory systems, experienced investigators, and well-developed research infrastructure. Asia Pacific continues to gain attention as sponsors access large patient populations, faster enrollment cycles, and operational efficiencies across China and India. Contract research organizations remain central to execution, supporting trial design, site management, data collection, and regulatory coordination.

Globally, clinical research is highly concentrated in a few developed regions. North America accounts for approximately 38% of the global clinical trial market, followed by Europe (27%) and Asia-Pacific (25%). Meanwhile, the Middle East and Africa contribute only approximately 10%, highlighting the gap in research activity across regions (Rawal and Tayade 2026).

Asia has emerged as the fastest-growing region for clinical trials. Over the last decade, the number of registered trials in Asia has increased sevenfold, with China, Japan, and India leading the region.

Despite this growth, clinical research remains unevenly distributed compared to the population size. For example:

Region	Share of Global Population	Share of Clinical Trials
North America	4.70%	20.10%
Europe	10.90%	18.40%
South Asia	25.30%	23.10%
Africa	18.70%	1.20%

This imbalance indicates that many populations remain underrepresented in global clinical research, which can affect the applicability of medical evidence across diverse populations (Pandey 2025).

Phase-based segmentation

Phase-based segmentation mirrors the drug development lifecycle and associated investment intensity. Regionally, the activity spans North America, Latin America, Western Europe, Eastern Europe, South Asia and the Pacific, East Asia, and the Middle East and Africa. Mature regions lead large-scale late-phase trials, while emerging regions contribute through faster recruitment, cost efficiency, and expanding clinical infrastructure. This structure highlights how sponsors balance scientific rigor, regulatory timelines, patient access, and operational scale across global programs.

Phase demand by the market

Phase 3 trials account for approximately 48% of total global clinical trial spending in 2026, making them the most

resource-intensive phase across the development lifecycle. These trials involve large patient cohorts, longer study durations, and rigorous endpoint validation to satisfy regulatory approval requirements. Budgets are highest at this stage due to multicenter coordination, complex protocol management, and extensive data monitoring obligations. Oncology, rare disease therapies, and advanced biologics continue to drive Phase 3 activity, as regulators require strong comparative and safety evidence before market authorization. While Phase 1 and 2 trials remain critical for early validation, Phase 3 dominance serves as the decisive commercialization checkpoint, where sponsors focus heavily on execution reliability, regulatory confidence, and risk mitigation (Evaluate 2026).

Clinical Research in Pakistan and the Region

Pakistan has significant potential to become a strong contributor to regional clinical research due to its large population, diverse disease burden, and expanding healthcare infrastructure. However, the country still participates in a limited number of clinical trials compared to its regional competitors.

Recent data shows that approximately 610 clinical trials were initiated in Pakistan in one year, while neighboring countries such as India conduct thousands of trials annually and generate billions of dollars from clinical research activities. (Medicine USNLo 2026)

According to clinical trial landscape reports, Pakistan has conducted around 3,800 registered trials, while China has conducted more than 40,000 trials, and India has conducted over 5,800 trials, highlighting the disparity in research capacity within the region (Pakistan Medical Research 2023).

Despite these challenges, Pakistan possesses several competitive advantages:

- **Large & treatment-naïve patient population**
- **Lower trial operational costs**
- **Increasing number of tertiary care hospitals**
- **Growing regulatory oversight by national authorities**

These factors position Pakistan as a potential emerging hub for clinical research if appropriate reforms and investments are implemented (GlobalData 2024).

Key Challenges in Regional Clinical Research

Limited Research Infrastructure

Many hospitals lack dedicated clinical research units, data management systems, and trained staff.

Lack of Trained Workforce

There is a shortage of trained clinical research professionals, such as CRCs, DMs, Biostatisticians, etc.

Limited Funding

Academic and investigator-initiated research often lacks financial support.

Low Awareness

Many healthcare professionals and patients have limited awareness about the importance and ethical conduct of clinical trials.

How Regional Clinical Research Can Improve

Building Research Infrastructure

Hospitals should establish dedicated Clinical Research Units equipped with EDC, Trained CRCs,, & Research Labs

Capacity Building and Training

Training programs in GCP, research ethics, and clinical data management should be expanded to develop a skilled workforce

Promoting Academic Research

Universities & hospitals should encourage investigator-initiated studies focusing on local disease burdens

International Collaboration

Partnerships with global pharmaceutical companies, CROs, & research institutions can accelerate technology transfer and capacity-building.

QUICK STATISTICS FOR CLINICAL TRIALS MARKET

Market Value (2026):

USD 131.8 billion

Market Forecast Value (2036):

USD 200.9 billion

Forecast CAGR (2026 to 2036)

4.3%

Key Growth Regions

USA, China, Western Europe, & India

Dominant Trial Phase by Revenue:

Phase III

clinical trials due to large patient volumes and regulatory requirements

Fastest-Growing Trial Phase:

Phase IV

trials supported by post-approval surveillance demand

Core Demand Drivers:

Oncology pipelines, rare disease trials, biologics development, post-marketing evidence needs

Leading Industry Participants:

IQVIA, ICON plc, Charles River Laboratories, PPD, Syneos Health

Future Outlook

The global clinical research landscape is evolving toward multi-regional clinical trials, in which multiple countries participate simultaneously in drug development studies. Emerging regions with large populations and diverse genetics are increasingly important for these trials (Wang et al. 2024).

If developing countries invest in research infrastructure, regulatory efficiency, and workforce development, they can significantly expand their participation in global clinical trials. This would not only strengthen healthcare systems but also bring economic benefits through research funding and innovation (Wang et al. 2024).

Conclusion

Regional clinical research is at a critical turning point. While developed countries continue to dominate the global research landscape, emerging regions, such as South Asia and the Middle East, have immense potential to contribute to medical innovation.

By improving regulatory processes, strengthening research infrastructure, and investing in human capacity, countries such as Pakistan can transform into competitive clinical research destinations. Expanding regional participation in clinical trials will ensure that medical treatments are developed using diverse populations, ultimately leading to more equitable and effective healthcare worldwide.

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Clinical Trial Landscape in Balochistan

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Background

Geographically, Balochistan is the largest province of Pakistan and remains one of the most under-represented regions in clinical research. Despite covering approximately 44% of the country's landmass, the province has limited participation in clinical trials due to its dispersed population, inadequate healthcare infrastructure, shortage of trained research personnel, and limited research funding. These challenges have restricted the development of a robust clinical research environment. However, the province also presents significant opportunities for clinical trials because of its unique disease burden, underserved populations, and unmet healthcare needs. (Wali et al. 2019)

Clinical Trials Conducted in Balochistan

Available evidence indicates that only a small number of interventional clinical studies have been conducted in Balochistan, with most focusing on infectious diseases, particularly cutaneous leishmaniasis and malaria, and various phase-III trial drugs under study. Examples include:

A. Safety and Efficacy of Miltefosine in Cutaneous Leishmaniasis: An Open-Label, Non-Comparative Study from Balochistan. The study was conducted on 42 patients for a period of 9 months. It evaluated the effectiveness and safety of oral miltefosine in patients with cutaneous leishmaniasis treated in Quetta. (Tahir et al. 2019)

B. Comparison of Efficacy of Intravenous versus Intramuscular Injection of Meglumine Antimoniate in Patients with Cutaneous Leishmaniasis. A randomized clinical study for a period of 7 months, including 90 patients, divided into 45 patients in each group. Comparing two routes of administration of meglumine antimoniate for treatment of cutaneous leishmaniasis (Ahmed et al. 2026)

C. Comparison of Intralesional Meglumine Antimoniate Along with Oral Itraconazole versus Intralesional Meglumine Antimoniate Alone in the Treatment of Cutaneous Leishmaniasis. The study was a randomized controlled trial conducted for a period of 5 months, including 69 patients in the study. The study assessed whether combination therapy improved treatment outcomes compared with standard therapy alone. (Bashir et al. 2019)

D. Efficacy and Safety of Artemether-Lumefantrine for the Treatment of Uncomplicated *Plasmodium falciparum* Malaria in Khyber District of Khyber Pakhtunkhwa and Zhob District of Balochistan, Pakistan. This study was conducted in District Zhob and District Kech in Balochistan under the observation of healthcare providers. The study evaluated the effectiveness and safety profile of artemether-lumefantrine in malaria patients from endemic regions. (Kakar et al. 2016)

Current Status of Clinical Trials

A review titled Clinical Trials Landscape in a Lower-Middle-Income Country (Pakistan) reported that Balochistan accounted for only about 30 registered clinical trials, highlighting the substantial disparity in research activity compared with other provinces of Pakistan. Most registered studies were concentrated in major urban centers and focused on infectious diseases, while non-communicable diseases, pharmacovigilance, and healthcare service interventions remained largely unexplored. (Mumtaz et al. 2024)

Research Gaps and Future Opportunities

Several areas require further clinical investigation in Balochistan, including: Diabetes mellitus, Hypertension, and cardiovascular diseases management in optimizing dose and adherence trials.

Anti-vascular endothelial growth factor (anti-VEGF) agents, including Bevacizumab and ranibizumab, are phase-III trial drugs used in Diabetic retinopathy trials, neovascular age macular degeneration (nAMD) management needs intravitreal injection safety studies, and comparative effectiveness trials. Although Bevacizumab was originally developed as an anti-cancer agent, it is frequently used off-label in ophthalmology due to its lower cost and comparable effectiveness. The anti-VEGF (bevacizumab) intravitreal agents are widely used in tertiary Eye care Hospitals of Balochistan.

Hepatitis B and C treatment outcomes should be evaluated based on medication compliance, implementation of advances in HCV pharmacotherapies (novel direct acing antiviral), monitoring adverse events, and better outcomes based on the World Health Organization (WHO) HCV-elimination strategy. (Ali et al. 2019)

Tuberculosis (TB) remains a significant public health challenge in Balochistan. The province's vast geographical area, scattered population, poverty, and limited healthcare access contribute to poor treatment adherence among tuberculosis patients. Revised guidelines of the WHO should be continuously followed in order to prevent multidrug-resistant tuberculosis (MDR-TB). (Rafique et al. 2024)

Implementing and expanding clinical trial activity in different divisions of Balochistan would generate locally relevant evidence, improve healthcare delivery, and contribute to reducing health disparities in the province. Balochistan requires greater inclusion in clinical research and clinical trials due to its unique demographic, geographic, and epidemiological characteristics. The province covers a vast geographical area with widely scattered populations, many of whom reside in remote and underserved regions with limited access to healthcare services. In addition, Balochistan hosts migrant and mobile populations, including internally displaced individuals and cross-border communities, whose health needs are often underrepresented in national research.

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Community Trials in Pakistan: An Overview

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Background

In clinical research, global academia is moving away from narrowly controlled hospital-setting clinical trials, towards pragmatic, community-based, and implementation-oriented clinical investigations in the real world. These trials assess the implementations by analyzing their effectiveness, feasibility, scalability and sustainability. This shift is pivotal especially for low- and middle-income countries (LMICs), where disease burden, disparities in health care access, social determinants of health, and resource scarcity have significant impacts on health outcomes. (Ford and Norrie 2016; Peters et al. 2013)

Pakistan is a very relevant community-based clinical research country, with a huge population, epidemiological diversity, a rapidly growing double burden of communicable and non-communicable diseases. An established primary health care outreach system, and urban and rural disparities, inequitable resource distribution along with high disease burden, further adds to favor of the above argument. (Pakistan Clinical Research Landscape Report 2025)

Unconventionality, number of population-based interventions developed over the years, have emerged in the context of public health interventions. The evolution of community-based research has been incremental since the late 1980s.The Expanded Programme on Immunization established foundational capacity in outreach, surveillance, and logistics. Building on this, the Polio Eradication Initiative (1990s) became a global case study in implementation research, advancing knowledge on vaccine hesitancy, GIS-based tracking, and decentralized delivery within complex sociopolitical contexts (Closser 2010). The Lady Health Worker Program (1994) further institutionalized community outreach for maternal-child health and subsequently served as a platform for cluster randomized trials (Hafeez et al. 2011). TB DOTS programs added capacity in treatment adherence and follow-up (Global Tuberculosis Report 2023). Most recently, COVID-19 has accelerated pragmatic, digital-health, and decentralized research models (Pakistan Clinical Research Landscape Report 2025).

While these initiatives substantially expanded healthcare coverage and community engagement, they also created opportunities for implementation research that were not always fully utilized. Compared with countries such as Iran and India, where public health interventions increasingly evolved into structured implementation science programs, many Pakistani initiatives remained embedded within service delivery systems without systematic evaluation of scalability, adoption, fidelity, sustainability, and long-term effectiveness. Consequently, substantial operational experience accumulated through decades of public health programming is not always translated into publishable evidence or policy-relevant research outputs (Peters et al. 2013; Proctor et al. 2010).

Current Landscape of Community-Based Clinical Trials in Pakistan

Community-based clinical trials in Pakistan have primarily addressed maternal-child health, infectious diseases, vaccines, and behavioral interventions. Bhutta et al. demonstrated that integrated perinatal/newborn care delivered by Lady Health Workers, traditional birth attendants, and community health committees significantly reduced perinatal and neonatal mortality in rural settings and proved feasible within primary healthcare systems (Bhutta et al. 2011; Bhutta et al. 2014). Soofi et al. extended this model by incorporating neonatal resuscitation and oral antibiotics into LHW services, improving survival outcomes (Soofi et al. 2017). The Community Level Intervention for Pre-eclampsia (CLIP) demonstrated that successful trials require integration with functional referral and health system infrastructure, highlighting the importance of implementation focus rather than intervention only. (Qureshi et al. 2020). Pakistan also pioneered the introduction for XDR typhoid (Batool et al. 2021) and implemented TB/tobacco cessation behavioral trials (Siddiqi et al. 2013). Evidence for community NCD interventions remains limited (Saleem et al. 2013).

Deficiencies in Published Community-Based Trial Research

Notwithstanding the significant improvements, there are still several significant gaps in the published clinical research environment within Pakistan at this level.

First, the published evidence is clustered on issues of infectious diseases and maternal-child health. Given the rapidly changing and elaborating burden of non-communicable diseases and psycho social stressors, this imbalance is of particular concern (Mirza and Jenkins 2004).

Second, many community intervention studies are geographically limited, donor driven, and are conducted as single center studies. There are comparatively fewer large multicenter pragmatic trials involving people living in rural, peri-urban and underserved communities questioning the generalization of results. (Peters et al. 2013)

Third, methodologies for implementation science are not well represented in many published interventions with little or no data into health systems integration. Furthermore, only few published studies explicitly utilize implementation science frameworks such as RE-AIM (Reach, Effectiveness, Adoption, Implementation and Maintenance) or the Consolidated Framework for Implementation Research (CFIR). Consequently, interventions are mostly evaluated on clinical outcomes, hence generating limited evidence in terms of sustainability, adoption barriers, and/ or health system integration. This, further, restricts their utility for policymakers seeking nationwide implementation of successful interventions (Glasgow, Vogt, and Boles 1999; Damschroder et al. 2009).

Moreover, longitudinal follow-up mechanisms remain inadequately incorporated within many community intervention studies. Most evaluations focus on short-term outcomes and provide limited evidence regarding the sustainability of behavioral change, intervention maintenance, or long-term population-level impact.

Another significant gap is that there is less representation for mental health and behavioral interventions. In the face of growing psychosocial factors, domestic violence, adolescent mental health problems, and disorders resulting from disaster and substance abuse in Pakistan, community-based mental health trials are still poorly represented in the country's literature (Mirza and Jenkins 2004).

Digital integration into community trials also is still limited. While COVID-19 pandemic has helped push the adoption of telemedicine and digital-health services, the integration of electronic medical records (EMRs), artificial intelligence (AI) supported surveillance systems, real-time monitoring, and adherence technologies is still underdeveloped (Pakistan Clinical Research Landscape Report 2025).

Although numerous community health interventions are implemented annually through governmental and non-governmental organizations, district health authorities, and academic institutions; many remain insufficiently documented within indexed scientific literature. This publication gap not only limits international visibility of Pakistan's community research contributions but also reduces opportunities for evidence synthesis, replication, and policy translation. Strengthening publication support, implementation science reporting, and collaborative dissemination mechanisms should therefore be considered an important component of future research capacity building. (Pakistan Clinical Research Landscape Report 2025; Peters et al. 2013). The principal challenge facing future community-based research is therefore, not merely the development of new interventions, but rather rigorous assessment of how effective interventions can be adapted, scaled, sustained, and integrated across diverse health system contexts (Milat et al. 2013).

Coordination of institutional, academic, regulatory, and policy-level interventions is required to strengthen the community-based clinical research ecosystem in Pakistan. Development of a national strategy to integrate community-based trials and implementation science within the national clinical research strategy in collaboration between the Drug Regulatory Authority of Pakistan (DRAP), Pakistan Health Research Council (PHRC), Universities, and Public health institutions in Pakistan is required. This would make it easier to standardize pragmatic trial methods, ethical considerations, community involvement, and evaluation of implementation (Peters et al. 2013; Proctor et al. 2010).

Importantly, there is a need to strengthen linkages between the learning from community trials and the scale-up of public health programs or policies to ensure evidence-informed decision-making. At the same time, increased efforts to disseminate scientific research, provide indexed publications, and editorial mentorship would enhance the international visibility of the community-based research contributions of Pakistan.

Conclusion

The evidence reviewed suggests that Pakistan's principal challenge is not the absence of community health platforms, but rather insufficient integration of these platforms into systematic research and implementation science frameworks. Existing programs and their embedded networks can provide a strong foundation for community-based clinical research.

The future success of Pakistan's clinical research ecosystem will, therefore, depend on its ability to transform operational experience into scalable, publishable, and

policy-relevant evidence capable of informing national health priorities. Addressing deficiencies in multicenter collaboration, implementation science capacity, digital infrastructure, longitudinal evaluation, and evidence-to-policy translation will be critical for transforming community interventions into sustainable health system improvements. Community-based trials should therefore be viewed not merely as an extension of public health programming, but as a strategic pillar of Pakistan's future clinical research ecosystem.

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Pakistan PPIE Experience: Ziauddin University

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Intrdocution

Patient and Public Involvement & Engagement (PPIE) represents a shift in mindset, where research is done '*with*' or '*by*' members of the public rather than '*to*', '*about*', or '*for*' them. In Pakistan, PPIE is gaining recognition as essential for ethical, inclusive, and impactful health research. Since 2023, Ziauddin University has developed one of the country's first structured PPIE programmes, centred on co-creation, shared decision-making, and meaningful participation.

Despite challenges including limited resources, variable research literacy, and sociocultural barriers, the Critical Care Research Group (CCRG) at Ziauddin University has developed a PPIE ecosystem that informs research priorities and regulatory discussions.

This section outlines Pakistan's emerging PPIE landscape through Ziauddin University's journey and key milestones.

Ziauddin University's PPIE Programme: Scope and Evolution

Established through the CCRG in 2023, the programme integrates patient and public voices throughout the research lifecycle from priority setting and proposal development to dissemination and implementation. It includes a PPIE lead, four coordinators and eight patient and public members, and has organised workshops, co-design sessions, and consultations for inclusive research.

Guided by the National Institute for Health and Care Research (NIHR) Standards for Public Involvement, the programme is built around five core principles:

- Recognition of Pakistan's PPIE innovations in regional and global forums
- Early integration of PPIE in the research lifecycle
- Partnerships between clinicians, researchers, and communities
- Co-development of culturally appropriate comm. tools for accessible science
- Diversity and expertise through lived experiences

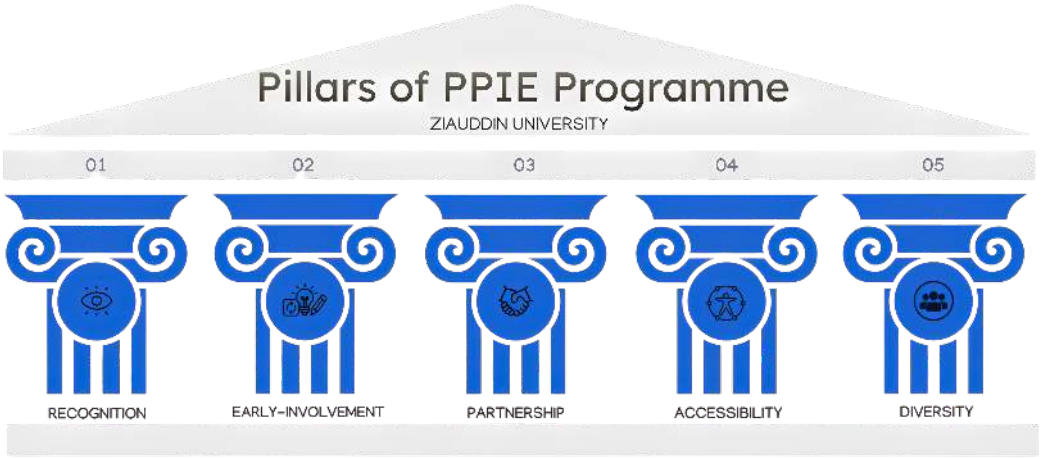

Figure 1. Pillars of the PPIE Programme at Ziauddin University

National Level PPIE Collaboration

A major milestone was the National PPIE Summit "Awaz-se-Aghaz", held on 1st November 2025, which brought together public partners, academic researchers, and clinicians, while opening dialogue with regulators, including the Drug Regulatory Authority of Pakistan (DRAP).

Representatives from thirteen institutions across Pakistan participated and committed to building a national PPIE network. This network will support resource sharing, collaboration, and peer-to-peer learning across institutions.

Ziauddin University's contribution includes developing a practical toolkit to guide institutions in establishing PPIE initiatives and collaborating with partners to integrate PPIE into research governance and policy.

International Recognition and Partnership

The programme has achieved international recognition for Pakistan-led expertise in public involvement. The team has contributed to international conferences, capacity-building initiatives, and working groups shaping trial design, including the International Pandemic Sciences Conference 2025, the Building Global Acute Care Research Capacity meeting in Kigali, and the Clinical Research During Outbreaks (CREDO) course. Members have also been elected to the International Trial Steering Committee of REMAP-CAP.

Key international collaborations include:

- MORU Community Advisory Board Network: Actively involved
- ISARIC: Leading in the South Asian Hub and supporting other Hubs
- InFACT: Leading the Global PPIE Thematic Working Group
- International Trials: Contributing to the Global Critical Care Patient and Public Advisory Group for PANTHER, PRACTICAL & REMAP-CAP trials.

The team has presented at global conferences and contributed to discussions on decolonising research participation and strengthening Global South leadership in PPIE. Programme projects have been endorsed by relevant partners, including OxTREC, MRINZ, ANZICS, and the Research Engagement and Involvement journal.

Outcomes and Impact

The programme has produced tangible improvements in research culture and practice:

1. Embedded PPIE into multiple research studies, where participant-facing materials were co-developed and approved by the Ziauddin University Ethics Review Committee.
2. Developed the ZU PPIE Toolkit and translated the MESH guide on advisory and involvement groups.
3. Produced videos, including "What is a Clinical Trial?" and "What is Mega-ROX?"
4. Strengthened a national community of practice through research collaboration agreements with two local institutions.
5. Generated peer-reviewed publications and protocols addressing PPIE implementation and evaluation in Pakistan and low-resource settings, including:

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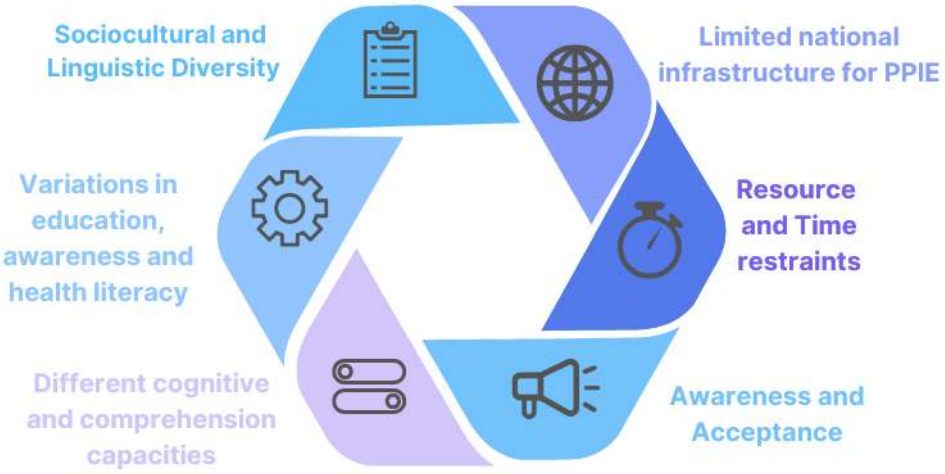

Figure 2. Challenges for PPIE in Pakistan

Implementing PPIE in Pakistan is challenging (see diagram), but it also offers unique learning opportunities.

Lessons Learned

Some key lessons are summarized below:

- Plain language, visual tools, and repeated engagement are more effective than technical written materials.
- Stepwise orientation and ongoing support enable collaboration.
- Power imbalances must be addressed to promote shared decision-making.
- Communication should be adapted to local languages and different reading levels.
- Effective PPIE requires dedicated human resources, funding, time and training.
- Flexible, responsive approaches are essential - A one-size-fits-all approach to engagement never works.

The Ziauddin University programme demonstrates that culturally grounded PPIE is achievable and impactful in low-resource contexts.

Future Directions

The next phase of Ziauddin University's PPIE programme focuses on:

- Raising awareness of infectious disease research among patients, families, and the public
- Building capacity through training, mentoring and development of practical PPIE resources
- Establishing a national PPIE network for research to support collaboration and knowledge sharing
- Improving evaluation tools to measure the impact of PPIE activities
- Deepening collaboration with regulatory and public health bodies, including DRAP and the National Institute of Health (NIH)
- Integrating PPIE into undergraduate curricula to support long-term capacity building in participatory research.

Conclusion

Against considerable headwinds, Ziauddin University's PPIE programme has emerged as one of Pakistan's leading examples of meaningful public involvement in research. Through national and international collaboration, inclusive practice, and a strong commitment to community voice, ZU continues to strengthen Pakistan's clinical research ecosystem.

"What my trial taught me that my medical school professors couldn't"
A medical student's view from the other side

Dr. Rabia Tassaduq, Sr. Clinical Research Associate, Clinical Trial Unit, National University of Medical Sciences

Background

This article features an in-depth interview with a medical student who is also actively participating in our Hepatitis C clinical trial. It was conducted to bridge the gap between abstract clinical data and real-world patient experiences. By highlighting a future doctor's dual perspective as both a subject and a healthcare trainee, this piece offers a unique look at trial participation in Pakistan, emphasizing the importance of patient-centric research.

PART ONE: THE PATIENT'S PERSPECTIVE

Hepatitis C (HCV) was not an unfamiliar disease to him. Both of his parents had been diagnosed with it, and his father, who was a doctor, had some knowledge of its treatment. So, when a first-year MBBS student from Kashmir, studying alone in Swat, was diagnosed with HCV in his very first semester of medical college, it was a disease he was familiar with, which made receiving the diagnosis less surprising but no less difficult.

His father's initial reaction was to prescribe him a medication he himself knew well. But a referral brought him to a clinical trial unit in Islamabad, where he was offered a choice: the familiar treatment or a newer, shorter-course oral regimen under investigation. He chose the trial. Not because his family encouraged it - they didn't. Not because the path was simple - it wasn't. He chose it because he had exams to sit, lectures to attend, and a disease to overcome as quickly as possible.

"My family didn't want me to do this," he said, "but I took a step for myself. I knew I didn't have much time as medical is a very tough field. I wanted to get this cured so I could focus on my studies."

What Nobody Told Him

He arrived expecting to collect his medication and return in three months for a final PCR. However, what he went through was a lot more demanding. Fortnightly appointments, blood draws at every visit, and a 3-4 hour long journey between Swat and Rawalpindi alone, often tired, sometimes in the middle of summer heat.

"The travelling was the most difficult part," he said. "Not the expense; the trial covered that. After the blood draw, I would feel weak, and then I still had to make the journey back. I was exhausted."

The response from his hostel mates was, in its own way, just as difficult to deal with. When his diagnosis became known, he found himself increasingly alone. Hostel mates distanced themselves. He was already far from his family, already navigating a new city and a new illness. The isolation made everything harder.

"If someone has an issue like this, please don't completely isolate them. Allow people to interact with them. Yes, take precautions but don't exclude them in a very obvious manner."

The side effects added to the burden. Early in the treatment, he experienced persistent headaches, myalgias, and leg pain. Those around him noticed something else: he had become uncharacteristically irritable, quicker to react, and short-tempered.

"People complained I was becoming aggressive," he recalled. "I don't know if it was a side effect, but it happened during that time."

As his body adjusted, things gradually improved. The fortnightly visits eventually became monthly ones, and with that, things became easier.

What Kept Him Going

What he describes as the most defining part of his experience is not the medication and not even the fact that his disease was being treated. It is the humanity with which the trial team treated him.

"They didn't treat me with pity. They treated me like a normal person who had a problem. When I had any issue, small or big, they were available. They guided me regarding what to do. I can't just call it a cure. It was more than that."

He had been told once, early in medical college, that ***"a doctor's attitude cures half a patient's disease".*** He hadn't believed it then. He believes it now. Watching how the team

responded when he missed a dose or experienced an adverse event, without blame, without coldness, shaped the kind of doctor he intends to become.

He hopes the drug he has been receiving as part of the study makes it to the market. Not as an abstract wish for science to succeed, but because he has lived its effects firsthand, and because he knows how many people in communities like his own are still turning to hakims or a herbal remedy before they consider a hospital.

"If this comes to market," he said, "I will be so happy. It worked for me. It should be available to everyone."

PART TWO: WHAT HIS STORY ASKS OF US

What he went through is not unique to him. It is a window into the everyday reality of clinical trial participation in Pakistan, and it raises several practical questions that research units, clinicians, and the broader medical community are responsible for addressing.

The logistical burden he described, consisting of long solo journeys, post-blood-draw fatigue and the struggle of fitting a research schedule around a full-time degree, is manageable, but only if it is anticipated and accommodated. Flexible visit windows, clear pre-visit briefings on what to expect physically and proactive check-ins between appointments are not luxuries. They are what keeps a participant engaged and committed. The fact that the trial covered his travel costs was, by his own account, genuinely important.

His experience with side effects, including the mood changes that people around him noticed before he connected them to the medication, points to the value of early, specific counselling on psychological and behavioral side effects. Patients are better equipped to manage what they can name. So are the people living and interacting with them.

On stigma: HCV is not transmitted through ordinary social contact, and yet the isolation he experienced in his hostel was real and harmful. Institutions, including medical colleges, have a responsibility to ensure that students and staff understand the actual transmission risks of blood-borne conditions and that precautionary measures should be rooted in scientific facts rather than being reflective of social discomfort. A socially isolated patient is a patient whose mental health is deteriorating, whose motivation to continue is fading, and who is less likely to complete the trial.

Finally, his observation about community attitudes to illness deserves thoughtful consideration. As shared by the patient, the belief that disease is a divine trial to be endured, rather than a condition to be treated, is not irrational within its own framework. But as his own choice demonstrates, faith and medical care can go hand in hand. The body, in Islamic thought, is a trust. Caring for it is an obligation. Community health communicators, and future doctors like him, who can speak that language from the inside, are among the most powerful tools we have to educate the community.

He is twenty years old. He has already learned what many physicians spend careers trying to understand: that while the science of medicine lives in the prescription, the art of it lives in the interaction. That lesson belongs not just to him; it belongs to every health professional that will ever ask a patient to trust them with their health.

Health Communication: The Missing Link in Pakistan's Clinical Trial Ecosystem

Dr. Madiha Siddiqi, Clinical Manager, Lung Health Program, Indus Hospital & Health Network

Background

When discussing clinical trials, attention naturally centers on the pillars of scientific rigor: study design, ethics approvals, statistical significance, regulatory compliance, and clinical outcomes. However, a critical dimension often remains in the shadows: the communication of research evidence across systems and its translation into trust, policy, and practice.

While Pakistan is seeing a positive shift toward Patient and Public Involvement and Engagement (PPIE) at the participant level, as highlighted by Tolppa et al. (2024), a broader systems question remains: *how far does our communication ecosystem extend beyond patients and academia?*

The Gap Beyond the Lab and the Journal

In Pakistan, most trial outputs remain confined to academic journals, technical reports, and scientific conferences. While scientifically essential, these formats are not designed for operational decision-making or public interpretation. Consequently, vital evidence often remains academically visible but operationally underused.

The communication breakdown is most acute across five critical nodes:

- Limited engagement of policymakers during the interpretation and translation of findings
- Minimal integration of media professionals within clinical trial communication strategies.
- Lack of structured, actionable synthesis for health system leaders
- Inconsistent engagement with donors & implementation partners regarding scalability
- Weak, fragmented loops between research environments and decision-making bodies.

As Pakistan seeks to expand its clinical trial capacity, strengthen indigenous research and attract international and local investment, strategic communication can no longer be an afterthought. Trials are far more likely to influence policy, attract funding, support scale-up and gain public trust when stakeholders understand both the evidence and its real-world implications.

Global Lessons: From "Dissemination" to "Integration"

Evidence shows that clinical trial impact is strongest when stakeholder engagement is embedded throughout the research cycle. Global frameworks highlight this shift:

- Canadian Institutes of Health Research (CIHR): Integrates knowledge translation across the entire research lifecycle, fostering early collaboration between researchers and decision-makers to align evidence with implementation needs while advancing clinical trials, knowledge mobilization, and health system innovation through structured engagement with federal, provincial, and Pan-Canadian partners (Canadian Institute of Health 2024)
- World Health Organization (WHO): Emphasizes structured multi-stakeholder engagement across the clinical trial lifecycle, including policymakers and funders, to align trials with health system priorities and generate actionable evidence (Research for Health 2024).

Experiences from regional and low- and middle-income countries further reinforce these principles:

- **India:** Collaboration between government health systems, academia, and research programs has accelerated translation of evidence into national TB, maternal health, and immunization programs.
- **South Africa:** Embedded engagement between HIV/TB researchers, health departments, and donors has reduced delays between evidence generation and guideline adoption.

Emerging evidence suggests that clinical trial findings are translated more effectively into policy when policymakers, regulators, and technical advisory bodies are engaged through structured evidence-review processes. For malaria vaccines, RTS, S/AS01 and R21/Matrix-M were reviewed by the WHO Strategic Advisory Group of Experts on Immunization (SAGE) and the Malaria Policy Advisory Group (MPAG), alongside implementation data from pilot programmes, informing broader policy adoption (Immunization 2024).

Similarly, evidence from the MATISSE maternal RSV vaccine trial was incorporated into WHO and regulatory deliberations through structured stakeholder review pathways. (Strategic Advisory Group of Experts on Immunization 2025).

Media engagement during COVID-19 vaccine trials played an important role in communicating emerging evidence and shaping public understanding and trust in vaccine research through collaboration between researchers, participants, and journalists (Patrick-Smith et al. 2024).

Tailoring Evidence to the Stakeholders

Different stakeholders require tailored evidence to support their roles in clinical trials, as a single one-size-fits-all approach is insufficient for relevance, usability, and timely action.

Table 1: Key stakeholder groups, evidence needs, and optimal communication channels for effective engagement and decision-making.

Stakeholder	Information Needs	Preferred Communication
Policymakers	Cost-effectiveness, feasibility, health system impact	Policy briefs, executive evidence summaries
Health System Leaders	Operational demands, resource allocation, training needs	Operational briefs, implementation roadmaps
Media Professionals	Clear public health context, objective interpretation	Press briefings, structured media kits, expert Q&As
Funders	Long-term value proposition, scalability, Return on Investment	Investment cases, sustainability briefs
Clinicians	Immediate practice relevance, safety profiles, patient fit	Clinical guidelines, peer-led webinars, point-of-care tools
Local Communities	Real-world relevance, safety, accessible clarity	Plain-language summaries, community town halls

Moving Forward: Blueprint for Pakistan

To translate Pakistan's growing clinical trial evidence into genuine gains in policy, practice, and health outcomes, the research ecosystem must pivot toward five structural priorities:

- Embed stakeholder engagement from study design through execution and post-trial translation
- Treat communication as a vital scientific and operational function, not a post-trial activity
- Expand engagement beyond PPIE to include policymakers, clinicians, health system leaders, media, and international and local funders
- Ensure continuous translation of evidence into policy, practice, and public understanding

Advancing these priorities and drawing lessons from more integrated global and regional research systems is essential to ensure that clinical trial evidence in Pakistan translates into meaningful improvements in policy, practice, and health outcomes.

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Clinical Research in Physical Therapy in Pakistan

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Physical Therapy is one of the emerging professions in Pakistan. The education evolved from a diploma programme to a 5-year graduate degree, Doctor of Physical Therapy (DPT). A National uniform curriculum was implemented through the National Curriculum Review Committee (NCRC-DPT) through the Higher Education Commission of Pakistan in 2011 (Parveen 2025). The education is available as undergraduate (UG), DPT degree, and postgraduate (PG), postgraduate Diplomas, Master of Science, Master of Philosophy, and Doctor of Philosophy degrees. Evidence-based practice and research are integral components of both the UG and PG curricula. For all PG degrees except PGDs, an interventional research project is mandatory to earn the degree (Osama, Malik, and Azim 2018). The publication of the findings from a clinical trial needs a prospective registration of the study protocol, is not only emphasized by ICMJE, WAME, and EMAME but the World Physiotherapy through the International Society of Physiotherapy Journal Editors (ISPJE) also recommends the same (Babu et al. 2013). Although most of the work of a physical therapist includes dealing with patients in the form of exercise interventions, preventive strategies, and patient education; yet some studies have been conducted to explore the effects of electrotherapeutic modalities and particular medications in specific conditions. Interventional studies in the form of randomized and non-randomized clinical trials or quasi-experimental studies are being conducted by the master's and MPhil scholars individually. The PhD scholars need to conduct an RCT to earn the doctorate.

Most of the institutions offering PG degrees own their institutional PRS accounts on the American Registry of Clinical Trials, clinicaltrials.gov (University of Health Sciences, Lahore, Riphah International University, The University of Lahore, Ziauddin Medical University, Karachi, etc.). During and after the COVID-19 pandemic, a fair rise was observed in the registration of study protocols on WHO-recognized free registries. The exact number of registered trials in the Physical Therapy domain can be inquired through the institutions directly.

An individual researcher has also utilized the Iranian Registry of Clinical Trials for more than 5 years, but since the war situation in Iran, the platform has not been accessible since 2025. Due to a lack of a national registry, Pakistani researchers have been utilizing the free platforms to register their protocols.

In Pakistan, being one of the lower-middle-income countries, there are very limited or no funding opportunities for physical therapists for their UG and PG research projects; ultimately, they prefer to conduct low-cost research projects. Although a few of the physiotherapist has won the NRPU grants from HEC in past years, there is a dire need for funding for the specialty (Wahid 2025). Similarly, the dissemination of the outcomes of the clinical research is limited due to no or very limited funding to bear the APCs of high-impact-factor, reputable journals by the institutions. The Allied Health Professionals Council of Pakistan (AHPC) has started serving as a regulatory body for physical therapists and all other allied health professions since 2023. There are high expectations that AHPC will formulate regulations for the monitoring of clinical research in the field of Physical therapy and all other AHP's (Tazion et al. 2025). Physical therapists lead physical activity interventions that can assist in preventing and combating the effects of non-communicable diseases (obesity, diabetes, etc.) and prevent long-term disabilities and the ultimate economic burden of these diseases (Mumtaz et al. 2024).

The evidence-based physiotherapy practice is mandated by the HEC through its NCRC and cannot be underemphasized. Cochrane Pakistan was launched in 2024 through the prestigious National University of Medical Sciences (NUMS) and will serve as a gateway towards evidence synthesis for Pakistani researchers (Khan et al. 2026).

There is huge potential in clinical research in Physical Therapy in Pakistan; capacity building, availability of resources, and legislation would facilitate the young graduates and the institutions to contribute in the national research landscape.

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A Fresh Graduate's Perspective on Clinical Research in Pakistan

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For many medical graduates in Pakistan, the traditional career pathway has long been centered on clinical practice. However, the rapidly evolving healthcare landscape is creating new opportunities for young physicians to contribute beyond direct patient care. As a fresh medical graduate entering the healthcare workforce, I view clinical research not merely as an academic activity but as an essential component of modern medicine that drives evidence-based healthcare, innovation, and improved patient outcomes.

Clinical research serves as the bridge between scientific discovery and patient care. Every treatment guideline, diagnostic tool, vaccine, and therapeutic intervention used in clinical practice today is built upon evidence generated through rigorous research. Yet despite its importance, clinical research remains an underexplored career pathway for many healthcare graduates in Pakistan.

The increasing globalization of medicine has highlighted the importance of research literacy among healthcare professionals. Whether pursuing postgraduate training, contributing to healthcare policy, or improving clinical outcomes, the ability to understand, interpret, and generate evidence has become a critical competency for modern physicians.

For many graduates of my generation, exposure to research often begins through academic projects, workshops, online courses, or mentorship opportunities. What initially appears to be a means of strengthening academic credentials frequently evolves into a deeper appreciation of how research influences healthcare systems. Through engagement with research methodology, scientific writing, and evidence synthesis, young physicians begin to recognize that medical progress depends not only on treating individual patients but also on generating knowledge that benefits entire populations.

This realization is particularly relevant in Pakistan, where the burden of both communicable and non-communicable diseases remains substantial and where many healthcare challenges require locally generated evidence to guide effective solutions.

Pakistan possesses several characteristics that position it as a promising environment for clinical research. The country has a large and genetically diverse population, a significant disease burden, an expanding clinical trial infrastructure, and growing regulatory support for research activities. The Pakistan Clinical Research Landscape Report 2025 highlights increasing numbers of registered clinical research projects, strengthening clinical trial units, and growing participation from local and international stakeholders.

Despite these developments, a gap remains between the available opportunities and the number of healthcare graduates actively pursuing research careers. Many students complete medical school with limited exposure to research methodology, biostatistics, clinical trial operations, and scientific communication. As a result, research is often viewed as a supplementary activity rather than a core component of healthcare advancement.

From the perspective of a fresh graduate, this gap represents an opportunity rather than a limitation. Expanding access to structured research training, mentorship programs, and practical research experiences can cultivate a new generation of physician-scientists, research coordinators, and clinical investigators capable of contributing to both national and international research initiatives

One of the most important lessons young healthcare professionals encounter is that research and clinical practice should not exist as separate domains. Evidence-based medicine requires clinicians to continuously evaluate emerging evidence and incorporate validated findings into patient care.

In many resource-constrained healthcare settings, there remains a disconnect between contemporary research findings and routine clinical practice. Strengthening clinical research capacity can help reduce this gap by generating locally relevant evidence, evaluating healthcare interventions within Pakistani populations, and supporting data-driven decision-making.

Young researchers can play an important role in this process. With growing access to digital learning platforms and research training programs, fresh graduates today have more opportunities than ever before to participate in systematic reviews, observational studies, clinical trials, and implementation research.

The future of clinical research in Pakistan will depend not only on infrastructure, regulations, and funding but also on the people who choose to participate in the research ecosystem. Encouraging students and fresh graduates to engage with research early in their careers can help build a sustainable workforce capable of addressing emerging healthcare challenges.

From my perspective as a fresh medical graduate, clinical research represents an opportunity to contribute to healthcare on a broader scale. It offers a pathway to generate evidence, improve clinical practice, inform policy decisions, and ultimately enhance patient outcomes. More importantly, it allows healthcare professionals to become active contributors to medical progress rather than passive consumers of knowledge generated elsewhere.

As Pakistan continues to strengthen its clinical research landscape, investing in the development of young researchers will be essential. The next generation of clinicians, investigators, and physician-scientists can play a pivotal role in ensuring that healthcare decisions are guided by high-quality evidence that reflects the needs of our population.

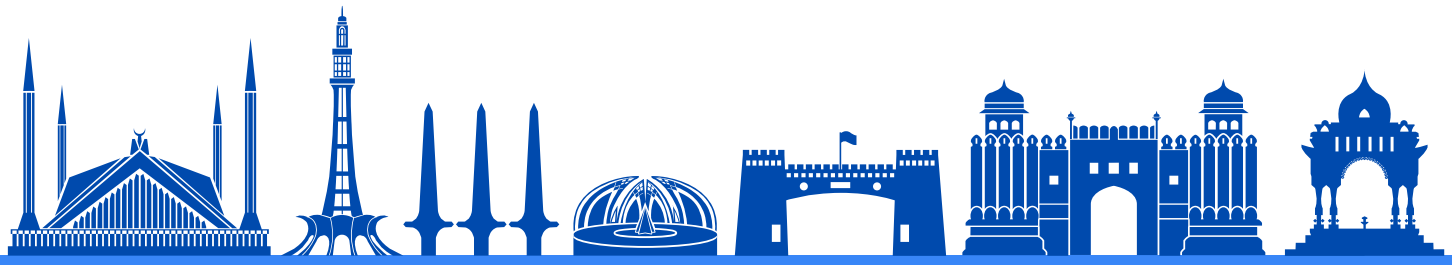
CONCLUSION & THE WAY FORWARD

The Pakistan Clinical Research Landscape 2026 document clearly demonstrates that Pakistan has crossed the threshold from capacity-building to execution. The foundational pillars of a world-class clinical trial ecosystem- regulatory clarity, ethical digitization, and robust site infrastructure- have been firmly established. However, securing Pakistan's position as a premier global hub requires moving beyond foundational reforms and embracing the next frontier of clinical innovation.

The path forward hinges on a strategic "virtuous cycle", where inherent capacity advantages (such as cost-efficiency and high recruitment velocity) are continuously leveraged to fund structural improvements, which in turn attract higher-complexity global trials. To sustain and accelerate this momentum, the following strategic imperatives must guide the ecosystem through the remainder of the decade:

1. **Digital Integration and AI Readiness:** While digital portals like NBC-R and PIRIMS have revolutionized regulatory submissions, site-level digital maturity remains uneven. The immediate focus must shift toward the nationwide standardization of EMRs and the adoption of cloud-based Clinical Trial Management Systems (CTMS). Bridging the rural-urban digital divide will enable the deployment of Decentralized Clinical Trials (DCTs) and position Pakistan to harness Artificial Intelligence for predictive patient recruitment and risk-based monitoring.
2. **Scaling Multi-Regional Clinical Trials (MRCTs):** With 64 MRCTs currently active, Pakistan has proven its capability to participate in global consortia. The next step is to actively transition local Clinical Trial Units (CTUs) from participating sites into leading coordinating centers for the MENA and South Asian regions. This will require sustained investment in Good Clinical Practice (GCP) workforce training, specifically targeting the acute need for specialized Clinical Research Associates (CRAs) and data managers.
3. **Public-Private Synergies and Commercialization:** To reduce the historical reliance on academic and non-industry funding, there must be a concerted effort to incentivize local and international pharmaceutical companies. Strengthening Intellectual Property (IP) protections and offering fast-tracked market registration for sponsors who conduct trials locally will stimulate commercial investment and drive the development of novel therapeutics tailored to the region's "double burden" of infectious and non-communicable diseases.
4. **Community-Centric Pragmatic Research:** As we globalize our standards, we must also localize our impact. Leveraging Pakistan's extensive community health networks—such as the Lady Health Worker Program—for pragmatic, community-based trials will ensure that research addresses the social determinants of health and yields interventions that are accessible to the broader population.

Pakistan stands at a strategic turning point. The challenges of the past are actively being dismantled by targeted investments and policy agility. By maintaining an uncompromising commitment to international accreditation, ethical oversight, and collaborative data sharing, Pakistan will not only secure its rightful share of the global clinical trial market but also fulfill its ultimate mandate: delivering equitable, evidence-based healthcare innovations to its people and the world.



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