Collaborating for Excellence, Strengthening Clinical Trials in Pakistan: Editorial Commentary

Sadia Hassan[1], Saeed Hamid[2], Zeba Aziz[3], Arishay Hussaini[4], Javed Akram[5], Irfan Ahmed[1]

Abstract

Pakistan, the world's fifth most populous country, has immense clinical research potential given its diverse population and high disease burden, particularly in endocrinology, neurology and cardiology. Progress, however, is constrained by inconsistent ethical review, weak infrastructure, and limited resources. Strengthening clinical trials requires training, strong governance, incentives for faculty, industry partnerships, and patient and public involvement. In July 2025, Pakistan Kidney and Liver Institute and Research Center hosted a national seminar to explore cross-collaboration and capacity building. The seminar's overarching goal was to highlight the importance of cross-collaboration and explore opportunities to enhance trial governance and capacity building. It aimed to coalesce discussions into a consensus statement that could guide national strategies for the ethical and efficient conduct of clinical trials in Pakistan.

Keywords: Clinical Trials as Topic; Patient Participation; Government Regulation; Organizational Capacity; Interinstitutional Relations.

Robust clinical trials are essential to establish the efficacy and safety of new therapies, advance healthcare and improve patient outcomes[1-3]. Globally, the number of clinical trials has risen, particularly after the COVID-19 pandemic[4,5]. However, in low and middle-income countries (LMICs), which house half of the world's population, fewer than 5% of trials are conducted, despite bearing a significant burden of disease[6,7]. Conducting clinical trials in Low- and Middle-Income Countries (LMICs) is essential. It requires careful planning to overcome challenges like limited infrastructure, fragmented regulations, and ethical complexities, but it offers vital opportunities to address the local disease burden and build research capacity. The World

[1] Pakistan Kidney and Liver Institute and Research Center (PKLI & RC), Lahore, Pakistan.
[2] Aga Khan University, Karachi, Pakistan.
[3,1] Hameed Latif Hospital & Pakistan Kidney and Liver Institute and Research Center, Lahore, Pakistan.
[4] Ziauddin University, Karachi, Pakistan.
[5] Akram Medical Complex, Lahore, Pakistan.

Corresponding Author

Sadia Hassan
Department of Research, Pakistan Kidney and Liver Institute and Research Center (PKLI & RC), Lahore, Pakistan.

Email: *sadia.hassan@pkli.org.pk*

Health Organization's (WHO) vision of being "always on" "always busy" necessitates capacity building[8,9], strengthened health infrastructure, efficient ethics review, research integrity and regulatory harmonization in Pakistan[10-16].

On July 25, 2025, the Pakistan Kidney and Liver Institute & Research Center (PKLI&RC) hosted a national seminar to discuss the state of clinical trials in Pakistan. The event paired together researchers, regulators, and industry representatives to shed light on the existing challenges and suggest ways to enhance the governance of trials, capacity building, and collaboration between the stakeholders.

The perceptive analysis and insights discussed in the seminar originated different themes. Prof. Irfan Ahmed highlighted the key factors caused by poor infrastructure and weak governance system as some of the factors contributing to the low global research share by Pakistan. Sustainable growth requires some essential ingredients including good governance, structured collaboration, professional training and active Involvement of patients and public in clinical trials.

Prof. Dr. Saeed Hamid provided careful appraisal of the status of clinical trials in Pakistan, noting that despite huge research potential, it has a limited footprint globally. Research, by and large, focuses on infectious diseases and oncology, neglecting high-burden conditions such as diabetes and heart disease in a heterogeneous treatment-naive population. Well-connected Clinical Trials Units (CTUs), efficient ethics and regulatory practices are the corner stone to enable Pakistan to emerge as a trusted international research partner.

The critical analysis provided by Prof. Dr. Zeba Aziz led to the observation of the steep drop in clinical trials due to our systemic neglect and failure to align with national health priorities, especially in oncology, where the burden is growing. She urged that locally owned research including investigator-initiated trials, facilitated by government and industry collaboration, is a dire necessity to stabilize research ecosystem in Pakistan.

Dr. Babar Saeed Khan was confident about the possibility of change in the clinical research landscape in Pakistan. The Association of Clinical Research Professionals (ACRP) Ambassadors Club Pakistan as the founding pilar, fosters momentum, builds international trust and suggests a growing trend towards professionalism. To maintain the momentum and qualify Pakistan as a regionally competitive hub, research excellence needs to be institutionalized by long-term collaboration, capacity building and synergistic efforts, instead of relying on the individual champions working in silos.

Regulatory excellence is the mainstay for global trust. Dr. Shafqat Hussain Danish, the representative of the Drug Regulatory Authority of Pakistan (DRAP), summarized the steps that were taken to make approvals and supervision of clinical trials easier. He informed that the publication of national clinical research guidelines proved to be a landmark step to conduct effective, ethical and internationally recognized trials. He was optimistic about building a culture where compliance is not an obstacle but the foundation of public trust and international credibility.

Prof. Javed Akram advised that in our country clinical research should also be aimed at patients with rare disorders, as it is not only a scientific possibility but a moral obligation as well. Researchers can establish a niche by investing in such underrepresented areas, which provide Pakistan with a bigger voice in global health. He introduced the first Rare and Genetic Diseases Summit, which was a milestone that the Society for Novel and Rare Diseases achieved in its quest to spread awareness and mobilize research in neglected fields.

Dr. Arishay Hussaini and her team have been actively involved in establishing the Patient and Public Involvement and Engagement (PPIE)[16] group at Ziauddin University. Their work has been transformational, embedding public and patient voices in research framework signals a shift from disconnected elitist research models to more equitable and patient-centered research paradigm in Pakistan. PPIE is not a process change, but a cultural change that renders research relevant, inclusive, collaborative and impactful.

The seminar concluded that efforts should be made to establish a clinical trials consortium in Pakistan, representing all key stakeholders in the research industry. It is equally important to establish inclusive structures by forming disease-specific study teams in neglected fields, such as endocrinology and rare diseases, to increase scientific influence and equity, as well as, to ensure patient and public involvement in all stages of trial planning. It was also agreed upon to strengthen the regulatory framework and simplify approvals of clinical trials. Capacity building is a need of the hour, it is time to initiate formal training programs at national level. Fostering academia-industry partnership and providing incentives to faculty participation in trials with research grants and educational credit also be an effective way forward.

The first landmark “Clinical Trials Summit” was held earlier this year in Pakistan at The Aga Khan University (AKU), Karachi, successfully organised by AKU in collaboration with the National University of Medical Sciences

(NUMS). The next summit for the year 2026 is being planned and will be hosted by NUMS in Rawalpindi, in collaboration with AKU. PKLI&RC also looks forward to contributing and welcomes the opportunity to host the 2027 Summit to extend the continuum of national partnership.

The seminar underscored both the vast opportunities and entrenched challenges in enhancing the clinical trials ecosystem in Pakistan. Pakistan now stands at a crossroads, whether to remain primarily a consumer of global science or to become a credible producer. Its path will not be guided by vision statements but by the continued institutional fortitude to change the potential into practice. Success depends on collaborative partnerships with local institutions and communities, using standardized and relevant measures, focusing on local capacity building, sufficient funding and translation of research findings into policy and practice to enhance health outcomes and equitable access to treatments.

PKLI&RC has been determined to support ethically sound, effective and efficient clinical trials that are responsive to national health priorities and help in advancing clinical research.

Acknowledgement:

I would like to acknowledge Dr. Baber Saeed Khan and Dr. Shafqat Hussain Danish for their valuable participation as speakers in the seminar, which enriched the discussion.

DECLARATIONS

Funding

The authors did not receive any financial assistance, grants, or external funding for the design, conduct, analysis, or publication of this study.

Data Availability Statement

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this study.

AUTHOR CONTRIBUTIONS

Study conception and design: *Sadia Hassan, Irfan Ahmed.*

Manuscript drafting and critical revision for important intellectual content: *Sadia Hassan, Saeed Hamid, Zeba Aziz, Arishay Hussaini, Irfan Ahmed.*

Manuscript review and editing: *Saeed Hamid, Zeba Aziz, Arishay Hussaini, Javed Akram, Irfan Ahmed.*

Final approval of the version to be published: *Saeed Hamid, Zeba Aziz, Arishay Hussaini, Javed Akram, Irfan Ahmed.*

Corresponding author and accountability: *Sadia Hassan.*

All authors approved the final version of the manuscript and agreed to be accountable for all aspects of the work, ensuring that questions related to the accuracy or integrity of any part of the work were appropriately investigated and resolved.

References

1. Sherin A. Clinical research in Pakistan: past, present and future prospects. Khyber Med Univ J. 2023 Mar 31;15(1):1–3. doi:10.35845/kmuj.2023.23355.
2. Jager W. The importance of clinical trials in advancing medical research. Ann Clin Trials Vaccines Res. 2023;13(3):93–8. doi: 10.37532/ACTVR.2023.13(3).93-98
3. Kandi V, Vadakedath S. Clinical trials and clinical research: a comprehensive review. Cureus. 2023 Feb 16;15(2). doi: 10.7759/cureus.35077
4. Fountzilas E, Tsimberidou AM, Vo HH, Kurzrock R. Clinical trial design in the era of precision medicine. Genome Med. 2022 Aug 31;14(1):101 doi: 10.1186/s13073-022-01102-1
5. Cortegiani A, Absalom AR. Importance of proper conduct of clinical trials. Br J Anaesth. 2021 Feb;126(2):354–6. doi: 10.1016/j.bja.2020.09.030.
6. Hackshaw A. A concise guide to clinical trials. John Wiley & Sons; 2024 Jun 10.
7. Audisio K, Lia H, Robinson NB, Rahouma M, Soletti G Jr, Cancelli G, Perezgrovas Olaria R, Chadow D, Tam DY, Vervoort D, Farkouh ME. Impact of the COVID-19 pandemic on non-COVID-19 clinical trials. J Cardiovasc Dev Dis. 2022 Jan 10;9(1):19. doi:10.3390/jcdd9010019.
8. Pakistan Clinical Research Landscape Report (Version 1). BMY Health & APPNA-MERIT; 2024 Feb. Available from: https://bmyhealth.com/wp-content/uploads/2024/02/Pakistan-Clinical-Research-Landscape-Report-for-version1.pdf
9. Mumtaz H, Haider SM, Neha F, Saqib M, Nadeem A, Seikha Z. Clinical trials landscape in a lower-middle-income country (Pakistan). J Clin Transl Sci. 2023 Dec 10;8(1):e7. doi:10.1017/cts.2023.701. Erratum in: J Clin Transl Sci. 2024 Feb 22;8(1):e35. doi:10.1017/cts.2024.22.
10. Hayat B, Mumtaz N, Choudry S, Khan MA, Butt AI, Chaudry ZA, Hussain M. Managing Clinical Trials Amid Healthcare Policy Reforms: Challenges and Opportunities. Pak J Health Sci. 2024 Nov 30:304–12. doi: 10.54393/pjhs.v5i11.2402
11. WHO. Pakistan [online feature story]. 2024. Available from: https://www.who.int/news-room/feature-stories/detail/pakistan
12. Moorthy V, Karam G, Karunakara U, Rottingen JA, Savulescu J, White NJ, et al. The future of the global clinical trial ecosystem: a vision from the first WHO Global Clinical Trials Forum. Lancet. 2024;403(10422):124–6. doi: 10.1016/S0140-6736(23)02798-8.
13. Fazal A. Ethical issues in conducting cross-cultural research in low-income countries: a Pakistani perspective. Asian Bioeth Rev. 2022 Apr;14(2):151–68. doi: 10.1007/s41649-021-00196-w.
14. Jafree SR, Zakar R, Fischer F. Ethical challenges of conducting clinical trials in Pakistan. J Pharm Policy Pract. 2019;12:29. doi:10.1186/s40545-019-0184-z.
15. Rathore FA, Farooq F. Research Integrity, Governance, and Misconduct in Pakistan: Some Proposed Solutions. JCPSP. 2023 Nov 1;33(11):1338–9.doi:10.29271/jcpsp.2023.11.1338.
16. Tolppa T, Hussaini A, Ahmed N, Dondorp AM, Farooq S, Khan M, Masood A, Murthy S, Saleem S, Shuja Z, Zaman S. Establishment of a patient and public involvement and engagement group to support clinical trials in Pakistan: Initial lessons learned. Res Involv Engagem. 2024 Sep 27;10(1):98. doi: 10.1186/s40900-024-00635-6.