Proceedings S.Z.M.C. Vol: 40(3): pp. 256-258, 2026. *PSZMC-1041-40-3-2026*

EDITORIAL

Building Clinical Trial Capacity in Pakistan: From Untapped Potential to Global Research Competitiveness

Ayesha Humayun[1], Salma Malik[2], Eman Ayub[3]

Affiliation:
[1]Shaikh Zayed Postgraduate Medical Institute, Lahore, Pakistan.
[2]Institute of Living/Hartford HealthCare, Hartford, CT, USA; University of Connecticut School of Medicine, Farmington, CT, USA.
Correspondence:
Dr. Ayesha Humayun, Professor of Public Health & Community Medicine, Director Clinical Trials Unit and Research, Chairperson & Dean, Shaikh Zayed Postgraduate Medical Institute, Lahore.

Every clinician carries memories of particular patients. Some are of relief, when a new treatment worked. Others are of loss, when there was no effective therapy to offer. Both leave the same question behind: could we have done better, or known more? Clinical trials are how medicine answers it. A vaccine that protects our children, a targeted therapy that shrinks a tumor, a simple drug that turns a chronic illness into a manageable one: each reached patients only after the long and demanding work of clinical research. That work is not evenly shared. Fewer than half of the clinical trials run by the world's largest pharmaceutical companies take place in low- and middle-income countries (LMICs), even though these countries are home to nearly 80% of the global population [1] Pakistan has, for too long, used evidence generated elsewhere instead of helping to create it.

The Clinical Trial Landscape in Pakistan

Clinical research in Pakistan has historically been concentrated in a small number of academic institutions and tertiary care hospitals. A review of trials conducted in Pakistan between 2000 and 2022 found that interventional research is held back by limited funding, a shortage of skilled personnel, and regulatory obstacles, and that most trial funding comes from Western funders or pharmaceutical companies [2].Pakistan's medical research output has grown quickly: Scopus-indexed medical publications roughly tripled between 2001–2010 and 2011–2020, and in 2019–2020 Pakistan had the second-highest publication growth rate of 46 countries analyzed [3]. Much of that growth, however, has been in observational studies and surveys. These have real value, yet they cannot answer the questions that only randomized trials can. Pakistan's share of international multicenter trials remains small for a country of its size, and worldwide, the growth in registered trials has been uneven across regions [2,4].

The COVID-19 pandemic showed both what Pakistan can do and how narrow its base still is. The international phase 3 trial of the single-dose Ad5-nCoV vaccine began enrolling in Pakistan in September 2020, before any other country, and Pakistan contributed the largest national share of participants to the efficacy analysis [5]. That achievement was the exception rather than the rule; the funding, staffing, and regulatory barriers described above still limit most institutions [2].

Why Pakistan Matters

Pakistan's value as a trial location starts with its population. Recruitment is one of the hardest parts of any clinical trial, and Pakistan's large and varied population gives access to patients across many disease areas. The country carries a heavy burden of infectious disease alongside rising rates of diabetes, cardiovascular disease, cancer, and mental disorders, which makes a wide range of therapeutic studies possible. Its tertiary teaching hospitals see high patient volumes and complex cases, and many of their clinicians have the expertise to contribute to international research collaborations.

From Potential to Preparedness

Moving from potential to preparedness starts with institutional commitment. Research is usually treated as the business of individual investigators, but a sustainable trial program needs an institution that owns it. Hospital leaders have to treat research as a strategic priority: commit dedicated resources, set up governance structures, and build research goals into the institutional plan. Ethical oversight matters just as much, because clinical research depends on public trust. Institutional review boards must review protocols rigorously, work

independently, and protect participants' rights. Pakistan already has a legal framework for this. Under the Bio-Study Rules, 2017, clinical trial sites must be licensed by the Drug Regulatory Authority of Pakistan, every trial needs independent ethics approval, and approved trials are entered in a national registry [6]. Compliance with these rules and with ICH-GCP should be part of everyday institutional practice, not a formality completed before an inspection.

Building Infrastructure

Trials need infrastructure well beyond what routine clinical care requires. A dedicated clinical research unit is the backbone of a modern program, with space for participant visits and informed consent, secure document storage, a research pharmacy, and access to laboratory services. Trials also depend on reliable systems for collecting, processing, storing, and transporting specimens, and studies involving biomarkers or biobanking need advanced laboratories with quality assurance. Digital capacity is now expected as well. Electronic data capture, remote monitoring, and secure databases are standard, and the World Health Organization (WHO) has called for wider use of digital tools and risk-proportionate monitoring [7,8]. Institutions have to invest in both the physical and the digital side.

The Research Workforce

The workforce often decides whether a site succeeds. Trials rely on multidisciplinary teams of research coordinators, study nurses, pharmacists, regulatory specialists, data managers, laboratory staff, and biostatisticians. Formal training in clinical research is scarce in Pakistan, and most health professionals pick up research skills informally or on the job. That is not enough for the demands of modern trials. Structured training programs, GCP certification, mentorship networks, and defined career pathways would make institutions far more ready; better mentoring and clearer careers for clinical researchers were among the main recommendations of an international workshop on research capacity in LMICs [9].

Culture matters too. Clinicians weighed down by clinical duties rarely find time for research, so institutions need to offer protected time, recognition, and career incentives. In a national survey of 380 Pakistani doctors, lack of training was the most frequently reported barrier to research (62.6%), and 48.1% cited inadequate support from mentors [10]. Behind these figures are thousands of young doctors whose research potential is going unused.

Quality and Credibility

Quality is what earns trust in clinical research. Sponsors look for institutions with strict regulatory compliance, reliable documentation, and sound quality management systems. Standard operating procedures, internal audits, corrective and preventive action plans, and monitoring are the tools an institution uses to earn credibility and keep it. The first WHO Global Clinical Trials Forum proposed a maturity framework to track how clinical trial units develop,[8] and WHO's 2024 guidance calls for quality management that is proportionate to risk [7,11]. For Pakistan, stronger quality management is one of the most effective ways to build international credibility and long-term partnerships.

A Roadmap for the Future

Becoming trial-ready is a gradual process. Leading research centers usually begin with governance and ethical oversight, then build infrastructure, train staff, and put quality systems in place. Experience with investigator-initiated and observational studies often comes before participation in large multicenter trials. At the national level, a coordinated network linking medical universities, tertiary hospitals, and community sites would improve recruitment, make multicenter studies easier to run, and give Pakistani researchers a shared purpose. The benefits reach beyond research: good governance, careful documentation, and a habit of continuous learning also improve patient care.

Conclusion

Pakistan has much of what it needs to contribute to global clinical research: a large population, a diverse disease burden, a growing academic sector, and a regulatory framework that is maturing. The Aga Khan University, the country's most productive medical research institution,[3] and the Pakistani sites in the international Ad5-nCoV vaccine trial [5] have shown that research to international standards is possible here when commitment and resources are in place. Turning that potential into routine practice will take deliberate and sustained effort. Trial capacity needs to move from individual investigators to institutional systems built on governance, infrastructure, workforce development, ethics, and quality. Clinical trials should be seen as an investment in healthcare innovation, scientific excellence, and national development. If Pakistan builds that capacity, it can move from consuming evidence to producing it.

REFERENCES

1. Access to Medicine Foundation. 2024 Access to Medicine Index. Amsterdam: Access to Medicine Foundation; 2024. Available from: https://accesstomedicinefoundation.org/medialibrary/2024-access-to-medicine-index.pdf
2. Mumtaz H, Haider SMA, Neha F, Saqib M, Nadeem A, Fahim A, et al. Clinical trials landscape in a lower-middle-income country (Pakistan). J Clin Transl Sci. 2024;8(1):e7. https://doi.org/10.1017/cts.2023.701
3. Hassan W, Ara A. Pakistan has the 2nd highest growth rate in medical sciences research publications for the year 2019-2020: comparison with 46 countries. Proc Pak Acad Sci B Life Environ Sci. 2021;58(3):43-54. https://doi.org/10.53560/PPASB(58-3)661
4. Viergever RF, Li K. Trends in global clinical trial registration: an analysis of numbers of registered clinical trials in different parts of the world from 2004 to 2013. BMJ Open. 2015;5(9):e008932. https://doi.org/10.1136/bmjopen-2015-008932
5. Halperin SA, Ye L, MacKinnon-Cameron D, Smith B, Cahn PE, Ruiz-Palacios GM, et al. Final efficacy analysis, interim safety analysis, and immunogenicity of a single dose of recombinant novel coronavirus vaccine (adenovirus type 5 vector) in adults 18 years and older: an international, multicentre, randomised, double-blinded, placebo-controlled phase 3 trial. Lancet. 2022;399(10321):237-48. https://doi.org/10.1016/S0140-6736(21)02753-7
6. Drug Regulatory Authority of Pakistan. Bio-Study Rules, 2017 (amended by S.R.O. 685(I)/2023). Islamabad: DRAP; 2017. Available from: https://www.dra.gov.pk/wp-content/uploads/2022/02/BiostudyRules2017-4.pdf
7. World Health Organization. Guidance for best practices for clinical trials. Geneva: World Health Organization; 2024. Available from: https://www.who.int/publications/i/item/9789240097711
8. Moorthy V, Abubakar I, Qadri F, Ogutu B, Zhang W, Reeder J, 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. https://doi.org/10.1016/S0140-6736(23)02798-8
9. Academy of Medical Sciences, InterAcademy Partnership for Health. Strengthening clinical research capacity in low- and middle-income countries: workshop report. London: Academy of Medical Sciences; 2017. Available from: https://www.interacademies.org/publication/strengthening-clinical-research-capacity-low-and-middle-income-countries
10. Khan ZA, Muzzamil U, Ahsan K, Khan A, Jawaid M. Barriers of conducting and completing research in Pakistan among doctors: a cross-sectional survey. Pak J Med Sci. 2025;41(3):886-90. https://doi.org/10.12669/pjms.41.3.10424
11. Moorthy V, Siegfried N, Amuasi J, Li J, Makanga M, Soares-Weiser K, et al. Improving the clinical trial environment and infrastructure: moving from global resolution to action. Lancet Glob Health. 2025;13(4):e608-10. https://doi.org/10.1016/S2214-109X(25)00012-9

The Authors:

- Dr. Ayesha Humayun, Professor of Public Health & Community Medicine, Director Clinical Trials Unit and Research, Chairperson & Dean, Shaikh Zayed Postgraduate Medical Institute, Lahore.
- Dr. Salma Malik, Professor of Psychiatry, Frank H. Netter MD School of Medicine at Quinnipiac University; Associate Professor of Psychiatry, University of Connecticut School of Medicine; Program Director, Child and Adolescent Psychiatry Fellowship, Institute of Living/Hartford HealthCare, Hartford, CT, USA.
- Ms. Eman Ayub, Managing Editor, Proceedings, Shaikh Zayed Postgraduate Medical Institute, Lahore.