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Editorial

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Advancing Clinical Research in Bangladesh: Bridging Evidence to Practice

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ABSTRACT

Bangladesh has a proud legacy of clinical research, from pioneering oral rehydration therapy to advancing affordable vaccines. Yet, despite strong institutions such as the Directorate General of Drug Administration (DGDA), the Bangladesh Medical Research Council (BMRC), and world-class centers like icddr,b, the translation of evidence into practice remains uneven. Fragmented ethics review processes, limited pragmatic trials, and unclear data governance continue to slow progress. With the global shift toward risk-based monitoring and equity-focused trial standards under ICH E6(R3) and E8(R1), Bangladesh has a unique opportunity to strengthen its research ecosystem. This editorial argues for a ten-point agenda, including professionalizing IRBs, embedding quality by design, modernizing data protection, and funding antimicrobial resistance (AMR) implementation research. By aligning governance, financing, and training with international best practices, Bangladesh can shorten the evidence-to-practice gap and position itself as a regional leader in producing research that directly improves patient care.

Keywords: Clinical Research, Good Clinical Practice (GCP), Evidence-To-Practice Gap.

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INTRODUCTION

Bangladesh's legacy in clinical research is undeniable. The development and global dissemination of oral rehydration therapy (ORT) saved millions of lives, and the country's cholera vaccine studies and community-based maternal health trials continue to be cited worldwide as models of applied science (icddr,b, n.d.). Today, two national institutions set the research agenda and regulate activity: the Directorate General of Drug Administration (DGDA) and the Bangladesh Medical Research Council (BMRC). DGDA reviews and authorizes trials, while BMRC defines priorities and leads the National Research Ethics Committee (NREC).[1] Together, these bodies form the backbone of trial oversight. Yet, the system is far from seamless. Institutional review boards (IRBs) vary in capacity, timelines are inconsistent, and coordination across sites is limited. While icddr,b and BSMMU demonstrate the ability to run world-class studies, that expertise is not evenly distributed across district hospitals or NGOs. Training pipelines—BMRC's regular workshops in Good Clinical Practice (GCP), biostatistics, and scientific writing, as well as icddr,b's fellowship programs—have helped expand the researcher base.[2] Still, the volume of registered interventional trials remains modest. Global trackers show Bangladesh underrepresented in late-phase studies that influence clinical guidelines. Bangladesh's readiness, therefore, is best described as a strong foundation with uneven reach. The country has capable regulators, proven investigators, and an ethical framework in place. But without streamlining processes and scaling capacity beyond elite centers, research risks remaining siloed—informative for science, but too slow or narrow to transform practice.

The Moving Goalposts: Global Standards with Local Implications

Global trial standards are shifting. The International Council for Harmonisation (ICH) has updated its cornerstone guidelines: E6(R3) emphasizes risk-based quality management and proportionate monitoring, while E8(R1) pushes for *quality by design* and broader inclusion of study designs and populations.[3] For Bangladesh, these

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changes are double-edged. On one hand, they raise the bar, requiring tighter data systems, clearer quality frameworks, and better documentation. On the other, they create space for pragmatic trials and context-relevant designs that reflect how care is actually delivered in district hospitals and community clinics. WHO's best-practice guidance goes further, urging that countries ensure trial populations mirror the people who will use the resulting treatments.[4] This call resonates deeply in Bangladesh, where rural women, the elderly, and people with multi morbidities are often excluded from formal research. Aligning national standards with ICH and WHO means not only compliance but also equity—ensuring that evidence reflects the needs of real Bangladeshi patients. DGDA's most recent GCP guidelines explicitly incorporate ICH language, signaling that Bangladesh is prepared to host multinational research to international standards.[5] This regulatory clarity makes the country more attractive for multi-regional clinical trials, while simultaneously strengthening domestic research. The challenge is implementation: training IRBs, hospital administrators, and investigators to translate abstract standards into daily trial practice. If done right, Bangladesh can position itself as both a regional hub for high-quality trials and a leader in ensuring evidence speaks directly to its own people.

The Evidence–Practice Gap: What Still Slows Translation?

Despite infrastructure and updated rules, translation remains slow. Ethics reviews can stretch for months, particularly when IRBs lack standardized operating procedures or sufficient trained staff.[6] This discourages multi-site trials and frustrates sponsors. Data governance is another major bottleneck. While Bangladesh has drafted a Personal Data Protection Act, it is still under debate and does not yet provide specific guidance for research use.[7] Without clear standards for lawful processing, secondary use, or data sharing, both participant trust and international collaboration are undermined.[8] Another problem is research focus. Many Bangladeshi studies are designed to test efficacy, but the most pressing health questions relate to *implementation*: how to deliver care reliably, affordably, and at scale. Antimicrobial resistance (AMR) illustrates this gap. Surveillance data show widespread resistance, but few trials test stewardship interventions in hospitals or communities.[9] Similarly, maternal and newborn care interventions proven effective elsewhere need to be adapted and trialed in Bangladeshi systems before policies can be updated. The net result is a frustrating lag. Studies generate statistically significant findings, but too often these remain trapped in journals or donor reports, rather than shaping treatment guidelines, reimbursement policies, or bedside care.

Closing this gap requires not only more trials but smarter designs, faster approvals, and a system that insists on implementation as the ultimate outcome. A clear path forward requires concrete actions that move beyond rhetoric and into reform. First, trial protocols must embed *quality by design*, identifying which factors are critical to quality and eliminating unnecessary burdens that inflate cost without adding value. Second, Bangladesh should prioritize pragmatic and hybrid trials, such as cluster-randomized or stepped-wedge designs, that test delivery strategies in real-world clinics.[10] Third, a Practice-Changing Trials Network—bringing together DGDA, BMRC, icddr,b, and NGOs—could pool resources through pre-approved contracts and shared monitoring cadres to speed implementation. Fourth, professionalizing IRBs through accreditation under SIDCER-FERCAP would harmonize standards and shorten review timelines.[11] Fifth, mandating prospective registration and timely reporting of trial results would improve transparency and public trust. Sixth, the pending Personal Data Protection Act must be modernized with explicit safeguards for research use. Seventh, antimicrobial resistance (AMR) demands immediate investment in stewardship trials linked to IEDCR's national surveillance sites. Eighth, strengthening the human infrastructure—through expanded GCP training, professional research coordinators, and district-level research facilities—remains vital.[12] Ninth, research must be directly linked to financing decisions, with a national Health Technology Assessment (HTA) unit ensuring that evidence informs reimbursement and coverage.[13] Finally, an evidence-to-action dashboard should tell the story transparently, tracking how findings flow into policy and practice.[14] Together, these ten reforms provide not just aspiration but a roadmap—achievable with political will—that can bring Bangladesh closer to a research system where evidence reliably drives patient care.

Special Contexts: Ethics, Consent, And Inclusion

Research ethics in Bangladesh cannot be divorced from context. The Rohingya refugee crisis illustrates the stakes. Reports of data collected without informed consent highlight how vulnerable populations can be exposed to harm when governance is weak. [15] Any research in such settings must prioritize voluntariness, confidentiality, and community engagement. BMRC's guidelines are a start, but practice must be strengthened with trauma-informed consent processes and independent. Equity is also broader than humanitarian work. WHO urges inclusive trial participation, yet women, older adults, and people with chronic conditions remain systematically excluded. This exclusion produces evidence that does not reflect the country's real disease burden. Designing for inclusion requires both regulatory encouragement and cultural change: IRBs must push investigators to justify exclusions, and funders should reward diverse recruitment.

Financing and Partnerships

Clinical research is not cheap, but the returns dwarf the costs. Establishing a national trials network, training cadres of coordinators, and modernizing IRBs will require investment. But these costs are minimal compared to the health system savings from evidence-based care and the economic benefits of attracting international trials. Domestic contract research organizations (CROs) and site management organizations (SMOs) already operate but need support to meet global standards.[16] Financing must come from multiple streams. Government seed funding signals seriousness and reduces risk for external partners. Philanthropy and diaspora capital can be mobilized for implementation research, especially for diseases underfunded by global donors. Development partners such as ADB or WHO can co-finance digital IRB platforms and trial registries. Above all, financing must be linked to accountability—clear metrics for trial numbers, diversity, reporting, and uptake into policy. Without that, money risks becoming just another project rather than a system-level investment.

What Success Looks Like in Five Years

By 2030, success should be visible. The number of pragmatic trials conducted in district hospitals should double, and IRBs should have SIDCER-FERCAP accreditation. A public evidence-to-action dashboard should track how studies inform DGHS guidelines. The Personal Data Protection Act should be enacted, providing trust in data use. AMR stewardship trials should be scaled across IEDCR sentinel hospitals, feeding directly into antimicrobial guidelines. And perhaps most importantly, frontline clinicians and communities should feel the difference—seeing treatments and practices grounded not in foreign data, but in evidence generated in Bangladesh.

Closing Argument: From Promise to Practice

Bangladesh has shown the world what is possible with simple, evidence-based solutions. The ORT packet remains the clearest example of research translating into practice at scale. But we cannot live off past glory. The challenge today is organizational: to embed quality, speed, equity, and accountability into the entire research system. Updated DGDA rules, BMRC leadership, global standards, and training pipelines are all in place. The missing link is coordination and political will. If we close the evidence–practice gap, Bangladesh can once again lead the world—not only in discovering solutions, but in ensuring they reach the patients who need them most.[17]

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