NAVIGATING REGULATORY HURDLES: A RETROSPECTIVE ANALYSIS OF CLINICAL TRIAL SUBMISSIONS TO NBC

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Objective

This study aimed to evaluate clinical trial applications submitted to the National Bioethics Committee (NBC) in Pakistan over the past five years, focusing on approval timelines, systemic challenges, and regulatory outcomes. The objective was to identify recurring bottlenecks and propose reforms for building a more efficient, transparent, and ethically robust review process that can support research growth in Pakistan.

Methodology

Data were collected from the NBC website, regulatory circulars, and published reports. Analysis included approval timelines, submission models, approval rates, emergency review mechanisms, and frequency of high-volume trials. Comparative assessment was performed between pre-2024 and post-2024 reforms, particularly the shift to parallel submissions with DRAP.

Analysis

NBC maintained transparent guidelines with timelines of 8 weeks (standard) and 2–6 weeks (expedited). However, delays were common due to redundant documentation, administrative burden, and sequential submission models. Approval rates remained steady, but inefficiencies were compounded by limited digitization, inconsistent IRB practices, and variable post-approval monitoring. Post-2024 reforms such as parallel NBC and DRAP submissions and streamlined pathways led to measurable reductions in turnaround times and improved predictability in reviews, though full benefits remain dependent on stronger oversight and system-wide coordination.

Conclusion

Reforms such as parallel DRAP and NBC submissions and streamlined pathways have shown measurable improvements. However, greater efficiency will require enhanced inter committee coordination, integrated digital systems, triage-based reviews, and stronger oversight to reduce turnaround times and build a more robust, research friendly regulatory environment for clinical trials in Pakistan.

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