

From Concept to Practice: Establishing a Clinical Trials Unit at PKLI&RC in a Resource-Limited Setting

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Clinical trials are widely considered as gold standard research studies for evidence-based decision making in healthcare practices¹. Clinical trials, however, are quite expensive, time consuming and involve a wide range of complex and closely monitored operations including regulatory approvals, initial screening, subject accrual, data collection interpretation and dissemination of results. Conducting clinical trials in low-middle income countries with resource limiting settings adds to this complexity². Clinical trial units are specialized medical research units that provide support and help clinicians and researchers to design and undertake clinical trial operations³.

The editorial aims to share the experience and efforts involved in the successful establishment of a Clinical Trials Unit (CTU) at the Pakistan Kidney and Liver Institute and Research Center

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(PKLI&RC), a milestone in strengthening clinical research infrastructure in Pakistan.

Recognizing the growing need for a compliant and well-equipped facility capable of conducting early- to late-phase clinical trials (Phase I–IV), our team embarked on the comprehensive process of setting up the CTU. This included detailed planning and extensive work to prepare the physical premises according to international and local regulatory standards. Special attention was given to aligning the infrastructure and operations with Drug Regulatory Authority of Pakistan (DRAP) guidelines.

Alongside facility development, dedicated significant effort was put forth to independently creating comprehensive documentation to support regulatory submissions and demonstrate operational readiness. This included Standard Operating Procedures (SOPs), CTU Manual and personnel training records, all tailored to meet Good Clinical Practice (GCP) guidelines and DRAP requirements.

To complement these efforts, I took the initiative to develop a video script and direct a comprehensive orientation video showcasing the CTU's capabilities, layout, safety measures, and



quality systems. The final production, completed in collaboration with the institution's marketing team, was presented during the DRAP site inspection. The video was well received by the inspector, who acknowledged its clarity and value in highlighting the site's preparedness and potential.

The successful outcome of the DRAP inspection reflects not only the meticulous groundwork laid in setting up the unit but also the importance of innovative communication tools in regulatory engagement. I hope this experience encourages and informs similar initiatives across the region, promoting the advancement of ethically sound and high-quality clinical research environments.

REFERENCES

1. Wang F, Wang X, Liu E, Song F, Chen Y. Impacts of clinical research units on clinical research-a systematic review of empirical studies. *Syst Rev*. 2025;14:94. doi:10.1186/s13643-025-02813-3.
2. Saluja T, Giri BR, Chaudhary S, Tamrakar D, Kanodia P, Palkar S, et al. Challenges and opportunities in setting up a phase III vaccine clinical trial in resource limited settings: experience from Nepal. *Hum Vaccin Immunother*. 2021;17(7):2149–2157. doi:10.1080/21645515.2020.1855955.
3. Gunter RL, Chouinard S, Fernandes-Taylor S, Wiseman JT, et al. Developing a clinical trial unit to advance research in an academic institution. *Contemp Clin Trials*. 2015;45(Pt B):270–276. doi:10.1016/j.cct.2015.10.001.

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