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EDITORIAL

Upholding the responsible conduct of medical research in Pakistan: The buck stops where?

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The clinical research landscape in developing countries continues to evolve and grow. The research output of low- and middle-income countries (LMICs) is further enhanced by international collaboration with the developed world. Lower costs, faster recruitment rate and relative ease in marketing approval are the main attractions for the global migration of clinical trials to LMICs.[1] Like other LMICs, Pakistan has made significant progress in mounting research output, specifically clinical research.[2, 3]

The Food and Drug Administration (FDA) of the United States does accept data from foreign studies conducted under the *investigational new drug* application, given that these studies meet the specific criteria outlined by the FDA. Regrettably, clinical research conducted in LMICs often faces challenges in gaining acceptance in the developed world.[4] Main areas of concern are related to ethical lapses in the research conduct, lack of consistency and trustworthiness of the data and methods, failure to follow the investigational plan and poor reporting of adverse drug reactions.[5] This lack of trust and confidence in research from LMICs is raising grave concerns about the equitable distribution of research benefits in terms of the availability of newly approved drugs among developed and less developed countries.[6]

To enhance the global acceptability of our local clinical research, we need to foster research integrity in Pakistan. Pakistan's leading clinical research stakeholders include regulatory bodies, healthcare institutions, hospitals and researchers. The Drug Regulatory Authority of Pakistan (DRAP) is the central body to regulate and oversees clinical research activities in the country.[7] Pakistan Medical and Dental Council (PMDC), primarily a licensing organization, indirectly influenced medical research by setting standards and guidelines for medical research and ethics in medical institutions.[8] Higher Education Commission (HEC) is a regulatory and funding body. It is vital to advance research and innovation in various clinical fields by supporting researchers and capacity building in Pakistan's higher education institutions, universities and research centres.[9] College of Physicians and Surgeons of Pakistan (CPSP) supports and promotes clinical research by including mandatory clinical research for postgraduate trainees and provides research methodology workshops and evaluation of protocols during fellowship training programs.10 Healthcare institutions, hospitals, research supervisors and researchers are the other critical stakeholders responsible for maintaining the utmost scientific rigor and ethical oversight of clinical research.

Earning a global reputation and achieving credibility in clinical research in Pakistan needs consistent and collaborative efforts to ensure ethical practices, adherence to the regulations, and the maintenance of high standards in conducting clinical research. This can be achieved by developing a culture of responsible conduct of research in our institutions and promoting the professional integrity of our researchers. Our primary stakeholders, like DRAP, PMDC, HEC & CPSP, are responsible for developing, disseminating and implementing clear guidelines, policies, and codes of conduct specific to clinical research in

Pakistan. Research institutions must establish research integrity offices for facilitating, monitoring and auditing research activities to ensure compliance with ethical standards and research integrity principles.[11] CPSP, the premier institution responsible for training future clinical researchers, contributes a lot to the training and supervision of clinical research. However, CPSP has to take essential steps for monitoring and auditing its trainees' research projects through supervisors and accredited teaching institutions. The role of supervisors and mentors is very critical, and they should take the responsibility of providing training and guidance to their trainees regarding research integrity by active engagement and monitoring of the research projects.[12] Research Ethics Committees need the special attention of DRAP and all other stakeholders to safeguard the research participants' health and rights and monitor adherence to the approved research protocol.

Institutions like HEC, CPSP, medical colleges and teaching hospitals must provide comprehensive training, education and professional development programs for clinical researchers. Recent progress in the establishment of clinical trials units along with collaboration with the Association of Pakistani Physicians of North America (APPNA) in the form of APPNA-MERIT, the start of the master program in bioethics and certificate courses in clinical trials and good clinical practice are very positive steps for the of clinical research landscape of Pakistan.[13] The prospects of clinical research in Pakistan and its credibility at the international level are up-and-coming. Pakistan has a growing healthcare infrastructure, a large population, and a diverse range of diseases and health-related challenges, which create ample opportunities for conducting impactful clinical research.

Overall, this is the collective responsibility of all stakeholders, including DRAP, PMDC, CPSP, healthcare institutions, hospitals, research supervisors and researchers, to promote responsible conduct in Pakistan's medical research and escalate the credibility of our clinical study globally.

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