

## Clinical Trials in Pakistan, missing opportunity

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*Madam*, Pakistan is sixth most populous country,<sup>1</sup> yet not well represented in clinical trials. No indexed publication exists, exploring the possibility of performing clinical trials in Pakistan to best of our knowledge. A careful examination of globalization of clinical trials trends reveals that despite the recent shift of more clinical trials from sites in established regions to those in developing countries, many large countries with huge potential of participation in clinical trials are still unrepresented. Pakistan is one such country where potential for participating in clinical trials remains untapped. This article also explores reasons for this adverse current trend and challenges to conduct clinical trials in Pakistan with an aim offer some potential solutions.

Geopolitical instability and underinvestment in health, by Government have resulted in serious gaps in health delivery, education, and research. Pakistan spends an amount on basic health which is less than the recommendation of WHO.<sup>2</sup> With the result public sector health care delivery cannot sustain the demand and quality.<sup>3</sup> Over past 69 years Pakistan's key health indicators lag behind when compared with other peer LMICs.<sup>4</sup> With basic unmet needs, enterprise of clinical trials remains neglected. It has never been prioritized, for funding opportunity or capacity building. Pakistan has a large pool of qualified physicians including those with research experience, however in Pakistan, government led platforms, as well as physician investigators initiated consortia and research groups do not exist. Absence of these national level collaborations lowers our prospects of being viewed internationally as potential research hubs which attract international collaborators. This further impacts the ability of physician investigators to lobby with government highlighting the potential gain of investing in the field of clinical trials, both financial and intellectual. Factors possibly linked with de-motivation of physician investigators could be lack of any research training and funding opportunity for physicians and that of support system to deal with huge paperwork, multiple approvals, regulatory complexities, contract negotiation process,

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associated with clinical trials, with no financial incentives and appropriate recognition of research efforts for career progression. Drug regulatory authority of Pakistan (DRAP), is surviving primarily on basic supply of drugs.<sup>5</sup> Similarly, local pharmaceutical industry is not positioned to keep pace with global counterparts in research and development.

Like other emerging destinations for clinical trials, Pakistan is in the position to offers high volume health care system with massive treatment naïve population, skilled physician investigators, low operational and investigator costs. With limited resources and current challenges, Pakistan hosted successful clinical trials collaborations, with academic organizations, making its place among highest recruiting countries, evidence that trials are not hindered by regulatory issues in Pakistan.<sup>6</sup> These trends suggest that stakeholders including Government, physician investigators, research organizations and pharma industry need to be engaged in serious discussion, to work towards national agenda at a common platform, to address factors internal to Pakistan. Strengthening infrastructure, regulatory environment, and research networks and incentivizing pharma industry and physician investigators are urgent needs to help clinical trials set up in the country. In addition to intellectual gain linked with research, clinical trials industry can reportedly serve as an important engine for sustainable economic growth,<sup>7</sup> which can help the economy of a country. While Pakistan deals with internal issues, Global clinical trials leadership is also responsible to ensure mechanisms to prevent underrepresentation of large populations, and see if any invisible barriers contribute to the situation.

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