LETTER TO EDITOR

Is India Quietly Becoming a Favourable Hub for Clinical Trials?

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Sir,

In recent years, India is becoming a go to destination hub for clinical trials.[1] There are a lot of reasons for this. India has a large and diverse patient population, which makes it easier to find wide range of patients for clinical trials. This diversity helps in giving the different genetic backgrounds and demographic groups which makes is more appropriate to study the effects of new drugs or treatments. India has a population of highly skilled healthcare professionals and researchers. Their expertise and experience contribute significantly to the clinical trials. The manpower, labour, patient recruitment, medical infrastructure is cost effective. India has a growing number of world class research facilities and hospitals well equipped with advanced medical technology which is essential for conducting high quality clinical trials.[2] Due to the large number of population and the disease burden, a greater number of patients are available to recruit in the trial and faster enrolment also reduces the time required to complete the clinical trials.[3]

India has a robust regulatory framework governed by the Central Drugs Standard Control Organization [CDSCO] and the Indian Council of Medical Research [ICMR].[3] Using various medical instruments and artificial intelligence to clinical research as well as medical services initiated by the Indian governments and ICMR.[4] These regulatory guidelines ensure the ethical conduct of trials and protect patients' rights and confidentiality. Regulatory bodies have put stringent measures in place to address ethical conduct to protect the rights and wellbeing of the participants with international standards of clinical research. The latest example of its efficiency was put to test during the COVID-19 epidemic. India was at the forefront of fight by quickly producing and testing the vaccines by clinical trials. The efficient system ensured not only quick results but also reliable when many in advanced nations failed.[1] It's also a rich ground for trials involving infectious diseases. As it's home to a myriad of infections. However unethical practices which can severely hamper the results and put the lives of the volunteers in danger. These remain the biggest challenges for clinical trials in India or anywhere.[5]

Since 2014, steadily the volumes for trials have been increasing. Especially after "New drugs and clinical trials rules" of 2019, India has become a preferred and attractive destination. The regulatory harmonisation has made it alluring to interested parties.[6] A February 2022 report according to Research and

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Markets states that the clinical trials market in India is valued at $2.07 billion and in 8 years it will expand at a CAGR of 8.2 per cent and will reach $3.88 billion by 2030. The "New Digital Personal Data Protection Bill 2023" will be soon tabled in the Parliament in July 2023. This will provide a clear framework for processing of personal protected data of Indian citizens.[7] It remains to be seen, that with government agencies focus on this sector, how much we as a country can further attract the trials and with time become numero uno in this sector.

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