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FACTORS RESPONSIBLE FOR GROWTH OF CLINICAL TRIALS IN INDIA

Social Science

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ABSTRACT

There is a surge in the number of clinical trials conducted in India since 2005. This is evident when one looks at the number of trials registered in the Clinical Trials Registry-India. Changes in rules and regulations guiding the trials have attracted different entities to conduct trials in India including foreign pharmaceutical industries. This paper discusses the various factors that led to the rise in clinical trials industry in India. Availability of cheap health care facilities along with less stringent legal and ethical framework regarding clinical trials in India is the major factor causing this high growth.

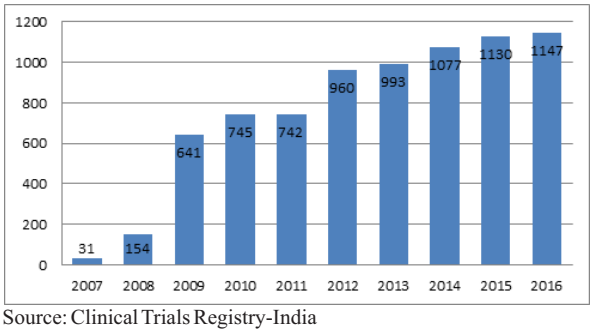
KEYWORDS:

Clinical Trials and Clinical Trials Registry- India.

I. INTRODUCTION

Advancement in the field of health services is possible through research and discovery of new treatments such as drugs and medical devices. Development of these new treatments should not only be effective to treat the disease but also safe to be used on humans. The test for efficacy and safety of these treatments are done through clinical trials. Consent to conduct clinical trials in India was given in 1988 by adding Schedule Y to the Drugs and Cosmetic Rules. Guidelines to regulate clinical trials were also formulated by this amendment. In 2005, the rules of Schedule Y were further relaxed by allowing clinical trials of the same phase (which is being conducted in some other country) to be conducted in India. This led to an increase of clinical trials in India since then. In 2007, Clinical Trials Registry-India (CTRI) was established in India. It was set up to make the trials more transparent and accountable such that the details of the registered trial could be accessed by all. As on April 2017, more than 8000 trials are registered in India. The following figure gives the number of clinical trials registered in the website since 2007.

Figure 1: Clinical Trials Registered in CTRI since 2007



Source: Clinical Trials Registry-India

As can be noticed from Figure 1, there is an upward trend of the registered trials. Since compulsory registration of the trials started since 2009, we see that during the year 2007 and 2008, a total of only 185 trials were registered. However, since 2009 to 2016, clinical trials have registered a growth rate of 9.08%. This phenomenal growth in the clinical trials provides the necessary impetus to study the factors causing it.

II. REASONS FOR RISE IN CLINICAL TRIALS IN INDIA

Patan et al. (2012) in their paper list the major reasons for the increasing number of clinical trials in India. The first reason they give is that India is one of the top five producers of bulk drugs in the world which automatically leads to demand for more and more internally induced research. It is estimated that the cost of clinical testing is approximately 70% of the total cost of developing a new drug. A major component of the cost of clinical trial is human resources. Therefore, another reason for growing clinical trials in India is that India is a site for cost effective human resources. Lower costs for labour, travelling, medication, hospitalisation, and investigation as compared to other countries are responsible for lower cost of clinical trials in India. This leads to global outsourcing of clinical trials to India. Also, in their paper, it is claimed that India offers appropriate infrastructure to conduct good quality trials which lures the multinational companies to conduct trials.

Rajan (2007) attributes the rise of clinical trials mainly to three local players. The first player is the Contract Research Organization (CRO) which provides support to the pharmaceutical industries in conducting clinical trials. Indian CROs is a growing industry and was estimated to be worth between $100 and $120 million in 2005 as reported from the estimate of Chemical Pharmaceutical Generic Association. They are the ones to receive immediate benefits from the growing clinical trials and thus they have an incentive in improving their service and infrastructure so that the demand for their services increases. Also the Indian patent law previously allowed process patent and not product patent, allowing pharmaceutical companies to reverse engineer generic versions of drugs. But after the WTO regime implemented the product patent in 2005, Indian pharmaceutical industries turned to increasing the research and development in the field of medicine to produce new drugs. Thus the pharmaceutical industries act as one of the players which are responsible for the rise of clinical trials in India. In order to increase the production of drugs particularly after 2005, it required greater use of CROs which in turn motivated the CROs to grow and thus clinical trials flourished in India. The final players are the regulatory authorities and the government of India. The DCGI has been actively regulating the norms of clinical trials in order to promote them and; the Ministry of Science and Technology is also investing into new institutes and training centers to improve the human resource so as to manage the trials better. According to the author, these players possess a common interest in promoting progressive research infrastructure as well as making India a favourable site for global trials. Apart from the above mentioned reasons for the increasing number of clinical trials, Bhowmik et al. (2010) points out that India has a large and diverse pool of diseases which attract global as well as local players to conduct trials. Since a majority of Indians belong to middle class, cheaper or free treatment (as mostly is the case in clinical trials) is always desired. People participate in trials for fatal diseases such as cancer and AIDS in the hope to get better. According to the authors, the reasons clinical trials are being diverted to India from other countries are as follows: i) India is emerging in the fields of information technology; ii) the number of English speaking educated population is growing in India and; iii) the infrastructure vital for conducting clinical trials is developing very fast in India. Important factors that make the multinational pharmaceutical companies difficult to conduct trials in the Western countries are the stringent regulations for conducting the trials and the complexity of the compensation principles. It makes the process of recruitment and approval too costly and lengthy. Indian government by providing Intellectual Property Protection from 2005 and relaxing the regulatory policies facilitated clinical research in India. Multinational corporations can now complete clinical trials in India facing very few restrictions. This is the reason why the growing awareness and implementation of Good Clinical Practices and ethical guidelines in India is causing resentment among the foreign pharmaceutical companies.

Dr. Surinder Singh, former DCGI, in addition to the above mentioned reasons, says that Indian population has six out of seven of the genetic varieties which makes the population heterogeneous and thus makes it ideal sample for conducting trials (Singh, 2013). Further he emphasized on the increasing number of life style diseases such as diabetes, depression and cardiac arrest in India which is responsible for increasing the numbers of clinical trials.

Bajpai (2013) made two important remarks on the reasons explored by different authors for the increasing number of clinical trials in India. First, the growing trend of clinical trials depicts that Indian medical training and the health services are getting increasing amount of western influence. Multinational companies generally manufacture drugs to treat western diseases and thus they are of limited help for the local Indian diseases such as malaria and kala azar. Thus, merely an expansion of the volume of medical research does not imply that India's health situation is improving. Secondly, if the Indian population is regarded as an ideal sample for clinical tests, it in itself shows the sorry state of poverty, lack of hygiene, and poor access to health services for the larger mass of the population. However, instead of tackling it, Indian government is promoting this fact worldwide to attract global clinical trials. The author also criticises the DCGI's intention of relaxing the regulations by the use of single window clearance and for fixing a deadline for approving new applications of clinical trials. At the time when all over the world, the regulations relating to clinical trials are being made stringent, India is doing just the opposite. It is to serve vested interest of the multination companies and these relaxation could disregard the humanitarian issues. CDSCO has been accused of corruption by the Parliamentary Standing Committee on Health and Family Welfare in 2012 when it was found that from 2008 to 2010, it cleared thirty one new drugs which did not even conduct any clinical trial. When there is evidence of malpractice by such a high authority, then corruption by other actors in the process is also inevitable. In this situation India should move towards making the regulations more stringent and thus serve the interest of the Indian masses rather than drug making industries. In fact, the author has asserted that the only reason that clinical trial industry is blooming in India is not due to cost advantage but that western multination companies are taking advantage of the Indian patent regime and lenient regulations.

III. CONCLUSION

The phenomenal growth in the clinical trial industry is considered a boon to the pharmaceutical industries (since clinical trials are largely funded by pharmaceutical industries) whereas; several concerns are raised regarding the ethical aspects of the trials which are largely ignored. Since humans are involved in clinical trials directly as participants, proper ethical norms should guide the trials. This aspect should not be overlooked while promoting this emerging clinical trial industry in India.

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