Clinical Trials Outsourcing: Globalization and Ethical Concerns

Outsourcing has been adopted in many industries as **a business strategic step towards globalization of actual practices and tendencies**. In the pharmaceutical world this trend can be absorbed as something relatively new. In order to produce a brand new medical product, pharmaceutical companies are expected to part with $1 billion on average. A huge percentage of these expenses is dedicated to human clinical trials as they have the most pivotal role before delivering a product to market. The increasing interest in global clinical trial outsourcing is **the result of drug makers trying to find an alternative which will help facilitate the overall production process of medicines.**

Faced with **numerous and strict regulations** in their home country, **drug makers are doing their best to speed up the whole process by redirecting their studies and trials** from already developed countries to still developing ones. As a consequence, regions such as India and others have turned into the most preferred places for offshoring clinical researches and product testing.

In the past decades, almost all of the clinical trials were carried out in the United States. Nevertheless, National Institutes of Health (NIH) stated that nearly 60,000 clinical trials were conducted in 173 countries outside USA between the years of 2000 and 2008. With India being the most frequently targeted country for clinical trials outsourcing**, drug makers are enabled to take advantage of several benefits**. First and foremost, in most cases drug producing companies see the offshoring of processes and procedures as a pure investment in terms of progress and development because India as well as other developing countries offer not only crucial savings on resources but savings on time too. **Other advantages include the fact that recruitment is envisioned to be consistently higher**. There are also concentrated health facilities and bigger population of potential

subjects who can participate in different researches. Finally, patients tend to be less mobile which makes it much easier for trial conductors to follow up the product testing.

With the advantages though, there come certain **ethical issues which raise a number of questions** regarding the outsourcing and globalization of clinical studies. Because many of these trials are performed in developing or third-world countries where the concentration of poor, uneducated and socially underprivileged people is much more intense, the researches can be seen as **exploitation and taking advantage of the vulnerable conditions of the participants**. To present this differently, since the local population lives on extremely low salaries, the funding provided by pharmaceutical companies to those who want to take part in clinical procedures is accepted as an exceptional opportunity for financial compensation. Hence, **participants discard the possibility of potential risks and negative effects which builds rather dangerous environment**. To avoid such outcomes, **stricter regulations should be applied to clinical trials offshoring** which will improve the collaborative work between locals and foreign pharmaceutical firms and organizations.

The evolution of Good Clinical Practice (GCP) demands a**dvanced approaches and outcomes which are not only more quickly distributed but also more efficient**. Outsourcing, then, becomes a strategy that answers for the progress of clinical trials. In order **to yield time-saving and cost-effective products**, the industry is focusing on carrying out researches in countries such as India. The rapidly growing interest of Pharma companies in non-traditional locations suitable for a variety of studies and medicine tests transforms into a mechanism that boosts productivity. And even though **there are diverse advantages for drug makers who conduct their activities outside the developed countries, offshoring clinical trials gives rise to concerns regarding human rights and ethics.**

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