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Clinical Trials Outsourcing: Good or Bad?

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Abstract

This paper describes what clinical trial outsourcing is. Is it good or bad?? How it is beneficial for industry? Authors want to show the two faces of the coin and want to investigate the both aspect of outsourcing.

Keywords: Clinical trials; Outsourcings; Regulatory requirements; FDA

Introduction

"Risk! Risk anything! Care no more for the opinions of others, for those voices. Do the hardest thing on earth for you. Act for yourself." [1]. On March 13, 2006, at 8 am, a drug was administered to eight healthy volunteers by intravenous infusion in the Phase I clinical trial at the research facility abutting Northwick Park and St. Mark's Hospital, London [2,3]. Within an hour after receiving the dose, six participants started complaining of a severe headache, backache, fever and pain. Even they threw off their shirts. The drug was attacking their immune systems and closing down the activities of vital organs. They all were experiencing the cytokine storm followed by nausea, headache, diarrhea, vasodilatation, erythema, and hypotension. By the evening i.e. after sixteen hours, volunteers were moved into intensive care. Some were in coma some were shouting and screaming. Then they became critically ill, some started showing signs of kidney failure, pulmonary infiltrates, lung injury and different intravascular coagulation. The drug was TGN 1412, developed by TeGenero Company based in Würzburg, Germany and the clinical trials were conducted by Parexel International Corporation situated at Lowell, MA [1].

Parexel International Corporation, an outsourcing CRO currently working in more than thirty nine countries, gave the study compensation fee of £2,000 to the patients [2]. But as per the regular trend for the phase one trial usually the compensation fees are £1000 to £1500 for one-two week study. So don't you think that the danger in the trial was pre-expected? Don't you think the safety and life of all those six patients were endangered? What would happen if that trial was conducted in India or Nigeria??

Whether the outsourcings of clinical trials in developing countries are publicized as per they are expected or the clinical trial results are buried under the files??

In the year 2010, Food Drug and Administration approved thirty five new drugs [3] and the IMS institute Health report claims that the pharmaceuticals global market size is expected to develop to nearly $300 billion and will reach $1.1 trillion in 2014. In last 15 years, there is about two hundred fifty percent augmentation, in number of clinical trials conducted all over the world. In addition to that the clinicaltrials.gov reported an accrual in the number of clinical trial submission from 10942 in 2006 to 17462 in 2010 [4].

On a contrary side according to Center Watch, Seventy Five percent of the general public state they have little to no knowledge about the clinical research enterprise and the participation process and Fifty seven percent of Americans say health-related research has helped them or someone close to them, but Ninety percent purchased prescription drugs for themselves or family last year [5]. Also in a report published by Research America, Charlton Poll, 2007, Forty percent of Americans say they would not like to participate in clinical research. Moreover, according to the survey organized by Clinical Research Enterprise and The Participation Process (CISCRP) on 1000 people in 2008 only Sixty Eight percent of people believe that clinical research studies and trials are somewhat or not safe [3]. What all these data implicate? This clinical trial process is really good or bad? Is this an inkling of opposing of clinical trials by future generation?

Unethical Outsourcing

Recently some cases of unethical outsourcing in India were in the picture. One of the cases includes the unethical clinical trials discreetly conducted on the Bhopal gas tragedy victims, without informing them and without asking their consents, in the Bhopal Memorial Hospital and Research Center (BMHRC). According to the reports, gigantic pharmaceutical companies like AstraZeneca, Glaxo Smith Kline, Pfizer etc. were unknowingly conducting ten different clinical trials on two hundred fifteen survivors of Bhopal gas tragedy from 2004 and 2008 [6]. The Official documents show that hospital director Maudar KK, accede to the Drugs Controller General of India (DCGI) that there were clinical trials and reported deaths in the three clinical trials of Fondaparinux (cardiology), Tigicycline (gastro surgery) and Televancin trial (anaesthesiology) [7]. According to NDTV news channel in 2011, occurred deaths were reported months later and in some cases, no reports were filed until two years had passed [7].

Specific core population was targeted in this outsourcing. In addition to that the subjects were not informed with the prerequisite information that is required by the various ethical guidelines. Even they failed to follow the legal regulation by not reporting the death in seven days happen during those clinical trials.

This shows that outsourcing treat the patients as guinea pigs. Today Pharmaceutical companies working culture is based on the bitter cited quote of Katherine Mansfield [1] mentioned in the starting, they do

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not bother for the regulations or law. They do not think for human safety. They are only bothered for finding core patients by the means of outsourcing for expanding research in specific countries. The company only concerns with the business; putting the minimum expenditure and getting maximum benefit, which can be easily achieved by outsourcing. So what actually this term outsourcing means?? What does it mean by the term outsourcing?

Outsourcing is the practice of contracting with another entity to perform services that might otherwise be conducted in-house [8]. Outsourcing in other terms can be defined as renting the experts and theirs skills rather than buying it. However the pharmaceutical outsourcing can be modified and defined as contracting with an independent organization to fulfill a specified and pre-defined prerequisites which are necessary for new drug discovery and development process. Now a day's outsourcing in pharmaceutical world is very common. It is like shopping the human like choosing the particular hen or body piece of hen for making the best cuisines.

Despite of several advantages there are many controversies for outsourcing. Let us judge every aspect of this issue, the pros and cons for conducting outsourcing. Let us see the both side of the coin for the outsourcing criteria which a pharmaceutical organization based in countries like United States looking in other companies or countries. There are many following criteria:

Outsourcing is money saving and time saving

"Cost saving and time saving is one of the major factor that led to outsourcing of clinical trials [9]."

Supporting statement: A pharmaceutical executive, reported that a case report charges for first-rate academic medical center in India is approximately $1,500 to $2,000, less than one tenth of the cost as compared to a second-tier medical center in the United States [10]. In addition to that developing nations are boon for cost reduction as the labor costs required for clinical trials are up to fifty to sixty percent cheaper here; moreover, there is an abundance of qualified and English-speaking doctors.

A huge expenditure and large tiresome process of clinical trials leaves a miniscule time for pharmaceutical firms to market and get benefit from the product. Beyond the saving in cash, the outsourcing fasten-up the process of clinical trials by recruiting copious and diverse subjects, something which is almost impossible in United States and in European countries.

Opposing statement: Other side of coin shows outsourcing as job-killing tactic for the skillful employees. Outsourcing is renting the other organization and their employees and such contracting policy can cause the reduction or job filtration of in-house employees for saving more money, more energy and more time and to get maximum benefit for combating in the market. For example, India, one of the top pharmaceutical outsourcing destinations for United States, has employed 340,000 workers in the pharmaceutical industry as of the end of fiscal 2009. The U.S. had a headcount of 277,200 pharmaceutical manufacturing employees as of May 2010, down five percent from 2007, according to the Bureau of Labor Statistics [11].

Speeding-up the clinical trial may lead to the recruiting and experimenting on more volunteers with a fast pace without giving a proper interval or time gap. Speeding–up the trial can endanger the patient safety; moreover, it can lead to incept unethical shortcut, TGN 1412 is an example that shows the consequences of speeding the clinical trial.

Moreover, according to http://economyincrisis.org, 1,742 drugs were recalled in 2009 while just 338 were recalled in 1999. The main reason is decrease in quality due to an augmentation in outsourcing in the decade. Untrained staff, ineffective laboratories, short deadlines and cheaper products all affects the quality of final product. Many firms outsource for curtailing the costs, but in the long run could end up paying for a lower quality drug [12].

Regulatory requirements

Outsourcing can help the organization to overcome the hindrance of regulatory requirements [13].

Supporting statement: The hindrance of regulatory requirement can be easily overcome by outsourcing clinical trials in developing countries. The phase II and phase III clinical trials can be easily conducted in the emerging nations with the permission of respective country's government and health authority.

Moreover, the outspread adoption of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Good Clinical Practice (ICH-GCP) guidelines and intellectual property protections in developing countries may also have contributed to the globalization of clinical research [7].

Opposing statement: According to several reports, recently governments in Latin America region have made considerable efforts to improve their health care regulations, including the gradual implementation of ICH-GCP guidelines in clinical research because their regulatory requirements did not meet with international standards.

Don't you think that this is the perfect example of Shopping? Countries are marketing them, enticing the pharmaceutical organizations by showing them several benefits, by truncating and modifying the regulations for getting outsourced. Don't you think it is like a Sabzi Mandi (vegetable market)? Don't you think countries are exploiting their population? Don't you think this is human exploitation or human trading rather than clinical trial?

Highly skilled physician, trained staff and the prerequisite of the advance logistics

Outsourcing also gives highly skilled physician, trained staff and the prerequisite of the advance logistics without any future commitments.

Supporting statement: Outsourcing provides the company to flourish new capabilities by expanding the knowledge base and acquiring new skills by hiring the highly skilled physician, trained staff and advance logistics. It facilitates the rapid exposure of modernized technology without committing resources to enrolling, training and managing, which enables efficiency gain by developing major changes in the experiment on a small scale [14].

In addition to that, outsourcing also provides the opportunity for the non-core organization to explore and concentrate on core capabilities by hiring highly expertize physician with tertiary care and specialty hospitals. For an instance Chinese CRO's tends to have stronger preclinical and superior offering in the field or target identification and validation as well as related areas of the field of genomics and proteomics [15]. Hence the outsourcing in china will provide a benefit of this core expertize. Outsourcing also helps in maintaining and focusing on the competencies in the market.

Opposing statement: This contracting method of hiring highly skilled physician, trained staff and advance logistics can cause several

problems also. First it leads to "dependence" on the specific country or organization which can lead to improper results or negligence and delaying of trial. Second, there are chances of data mishandling and loss in competition when the core subject or specific hospital is targeted for outsourcing. For example in case of BHRMC clinical trial the number of physician, staff member and available logistics are limited. The chances of leakage of company's discreet information are augmented which can be very dangerous for any the organization. Moreover it will be hard to monitor the performance of the physician or the outsourced organization. There are always communication gaps, language barriers and geographic discrepancies.

Conclusion

Despite of several advantages is this outsourcing procedure really useful for checking the safety and efficacy of the drugs??

If yes, then why there are so many recalls?? Why there are so many tragedies?? Why the results of clinical trials conducted in India and Nigeria were always hidden for a longer period? Are these outsourcing are done after fulfillment of all the prerequisite regulations? Are these trials were always done with the proper informed consent? What if the TGN happens in Nigeria or India? Did it publicize that much? Don't you think the clinical trial designs are done on the basis of outsourcing or the way to get maximum business profit without concerning about the safety and efficacy of patients?? Don't you think outsourcing policy only sticks to the benefits for the organization; the business or monetary benefits; benefits to reach of the apex of the pharmaceutical competence; benefit by extracting the poor, illiterate and needed population by giving them lucrative offers. Don't you think the working objective for the outsourced organization is to sell the country's population for the benefit of other country or organization? Don't you think whole process is only business? Don't you think the human safety and human rights are exploited and endangered by these outsourcings.

First of all, the outsourcing should be minimized in the developing nations. Moreover, the deigned regulations should not allow any compromise with the human safety. The job opportunities should not be curtailed even if the outsourcings are done. In addition to that the human volunteers should be treated with respect and they should be properly informed or consented before doing any research over them.

In conclusion the cases like TGN 1412 and Bhopal gas tragedy are eye-openers for the world, such cases are just a beginning or an end for those tragedies? The augmentation of pharmaceutical industry can be a boon or disaster?? All these are always unanswered question; however by maintain proper harmonization and respecting humanity the world will become a better place to live.

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