Ethics of Offshoring Clinical Trials

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Why it is Appropriate for Companies like Novo Nordisk to Conduct Trials in India

It is indeed appropriate for companies like Novo Nordisk to conduct trials in such countries as India. It ensures that trials are conducted by qualified staff in larger numbers of patients with a wide range of medical conditions. Novo Nordisk should conduct trials in India to examine the efficacy of its medications under different contexts (Delios, 2012). The variation in genetic, dietary, climatic, and other environmental conditions ensure that the effectiveness of these medications is determined locally in certain countries, such as India.

Novo Nordisk should conduct trials in India, where doctors and physicians are guided by medical ethics, based on the Hippocratic Oath that commits them to treat each patient irrespective of the country of origin to the best of their ability, and maintain patient confidentiality. Ethically, appropriate handling of clinical trials is important to Novo Nordisk (Delios, 2012). The trials conducted by the company follow a common protocol; hence, ensuring that the same standards are employed in all trials.

The Principles that Should Guide Such a Decision

Although the pharmaceutical industry has been accused of conducting trials in developing countries such as India without consideration of the ethical principles, it is important to note that major and global companies such as Novo Nordisk are guided by medical ethics in their trials (Delios, 2012). To counter all these allegations, professional medical organizations have come up with guidelines and principles of ethics to lead their research.

The decision of conducting medication trials in developing countries should be guided by the principle of voluntary informed consent, respect for patients, and the principle of independent review. Delios (2012) noted that under the principle of voluntary informed consent, the patients

have to ascertain willingly to take part in the research based on being fully informed about the purposes of the research and the potential risks that may arise. The principle ensures that medical research practitioners come up with an informed consent document that indicates to the subjects of potential risks and benefits of conducting the research in the area (Delios, 2012). On the other hand, the patients should sign the document before the commencement of the trials.

The second ethical principle that should guide the decision of conducting medical trials in countries such as India is respect for patients. The principle ensures that the privacy of the subject is protected and guarantees that patients are free to withdraw from the trials at any time (Delios, 2012). The ethical guideline makes secure that doctor's professional responsibility to the patient takes the first priority over all other considerations.

The third principle that should guide the decision of conducting medical trials in developing countries is independent review. Delios (2012) indicated that the principle ensured that all medical trials conducted in developing countries were assessed on the basis of scientific merits and ethically by an independent review board. It means that the experimental procedure should be clearly formulated in a corresponding protocol. The board that mandates the task of conducting the reviews should be in conformity with the laws and regulations of the country, in which the research experiment is conducted (Delios, 2012). The trials should be carried out by scientifically qualified individuals and under the supervision of competent medical personnel.

How Trials Should Be Managed and the Standards to Be Applied

Trials conducted in emerging economies should follow a common protocol, and therefore, the researchers must apply similar standards in their home countries and emerging economies. Trials should be conducted on those drug users, who later on become real consumers (Delios, 2012). At the same time, trial patients should have access to the medications after the

trial period has been completed. Pharmaceutical companies should conduct trials in countries where it has partners with the required knowledge and skills to carry out and monitor the trials. The relationship between the physician and subject should be governed by the physician's responsibility to care for his or her patient (Delios, 2012). The trials should be well managed with the use of active controls, in which control groups obtain a previously marketed medication with known properties. Placebo trials should only be used for diseases, in which patient conditions are improving because of the positive effect of receiving a form of treatment, rather than the specific medication.

Organizations should apply ethical standards designed to ensure the safety of subjects, integrity, confidentiality and wellness of all human beings taking part in the trails in emerging economies (Delios, 2012). Physicians should not carry out research unless they establish the risks involved, and determine whether they have been adequately assessed and well managed. Delios (2012) noted that trials should be stopped if the potential risks outweigh the benefits to the patients. The patients used for trials should be volunteers and should be informed about the research project. The trails should use valid measurements, statistical techniques and samples that are unbiased and sufficiently large, so that they can generate trustworthy and valid results (Delios, 2012).

Trials should be conducted in emerging economies if the medical results of the study are advantageous for the local population (Delios, 2012). Companies must ensure that physicians and researchers involved in the trials sign the Hippocratic ethics document, so that they can be held accountable if the trials pose major risks to patients (Delios, 2012). The principle of voluntary informed consent, respect for patients and independence are essential and should be enforced in developing economies while conducting the trials. It is because past incidences,

where these principles had been violated, continue to affect popular perceptions of medical research.

In conclusion, attaining ethical balance ensures that Novo Nordisk trials provide solid evidence of the effects of the new drug, and thus, protect potential future users of the given drug. Pharmaceutical companies should audit 10% of all trials to identify ethical problems in clinical trials of the developing countries. Finally, on ethical reasons, organizations must ensure that the same standards are applied for both developed and emerging economies.

References

Delios, A. (2012). *International Business: An Asia Pacific Perspective* (2nd ed.). Upper Saddle River, NJ: FT Press.