

Ethical practices guide medical research

Demands for greater accountability and transparency are rising, with companies expected to show how they ensure ethical considerations in the process of bringing products to market.

Healthcare companies hold a unique ethical responsibility by the very nature of their business. While regulatory authorities monitor that research is conducted in accordance with relevant laws and universal principles, stakeholders also seek reassurance that companies consider any ethical concerns that may emerge. In particular, this is a matter of being respectful of the integrity of people participating in medical studies, animal welfare and culturally founded objections to certain types of research.

Disclosure of clinical study results

The pharmaceutical industry came under fire in 2004. It was suspected of not making all results publicly available from its clinical trials, particularly results compromising the market value of its products. One response was a decision by the International Committee of Medical Journal Editors (ICMJE) to only publish clinical trial results from trials that had been registered in a public database at their inception. The US National Institutes of Health (NIH) extended their site for use on a global scale – www.clinicaltrials.gov. Additionally, the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry association, established a site to hold clinical information and references to publications, and requested its member companies to include all clinical trials finalised after 1 October 2002 for marketed products (www.clinicalstudyresults.org). Novo Nordisk complies with the ICMJE requirements and also posts its trial results on the PhRMA site. The ICMJE requires the registration of trials that started recruiting on or after 1 July 2005. Because many ongoing trials were not registered at inception, the ICMJE will consider for publication ongoing trials registered before 13 September 2005. Novo Nordisk has met both deadlines, with 51 trials of compounds registered at the NIH site by the

end of 2005 and 73 trials for marketed compounds posted on the PhRMA site.

"Honest and full disclosure of all studies is an important first step towards transparent and ethical practices. What we need to do next is to establish a mechanism for independent validation and a body to monitor and execute any required sanctions," says Torben V Schroeder, member of the ICMJE and editor of the *Journal of the Danish Medical Association*.

Informed consent

The principle of informed consent is at the core of human drug testing and is contained in guidelines endorsed worldwide, such as the World Health Organization's Helsinki Declaration. These rules prohibit coercion and trickery, and give patients the right to withdraw from a trial at any time for any reason. A hotly debated topic is whether informed consent can be upheld in countries where the participants may be impoverished and illiterate or where government ethical oversight may be lacking or limited. Obtaining informed consent also presents dilemmas, such as in cases where patients' condition makes them unable to give informed consent.

"Novo Nordisk ensures that the people participating in the trials are given detailed information both verbally and in written form. We provide information on the purpose of the trial in the native language, both the potential risks and benefits of participation," says Anders Dejgaard, chief medical officer in endocrinology reporting, Novo Nordisk. "We make sure that illiteracy, poverty or cultural barriers do not prevent a person's full understanding of the issues involved in participating in a clinical trial. Moreover, we only initiate trials in countries that can provide approval from an external local ethical committee."

Leading standards for animal welfare

The use of animals is essential for the discovery, development and production of pharma-

ceutical and medical products, and is required by regulatory authorities. However, it is also a source of concern for many people. That is why animal experimentation is one of the industry-specific reputational risks identified by financial analysts. They want to see evidence that companies duly consider this issue, and are also vigilant in looking for best practices.

Novo Nordisk has a long history of engaging with stakeholders such as animal welfare organisations to find solutions for improving the welfare of experimental animals. The company recognises that not all animal experiments can be replaced in the foreseeable future, but will only use animals where no available and acceptable alternative exists. With its ongoing commitment to finding new ways to replace, reduce and refine the use of animals for testing (the three Rs), Novo Nordisk has been setting new standards in this area. One example is the state-of-the-art housing standards.

Due to a higher activity level in the discovery phase in 2005, there was a 22% increase in the number of purchased animals, from a total of 47,311 to 57,905 animals, of which 97% are

mice, transgenic mice and rats.

Novo Nordisk is the pioneer of a new discipline called biosimulation, which involves computer models that simulate human beings as closely as possible. In the long term, biosimulation can lead to fewer and better experiments on animals, and fewer people will be needed for clinical trials of new drugs. Novo Nordisk is the only healthcare company participating in a new, EU-supported network of scientists working on biosimulation.

Full disclosure of clinical trial results ensures that the public can access information that helps shape medical decision-making.

Anders Dejgaard
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