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Safe Clinical Trials

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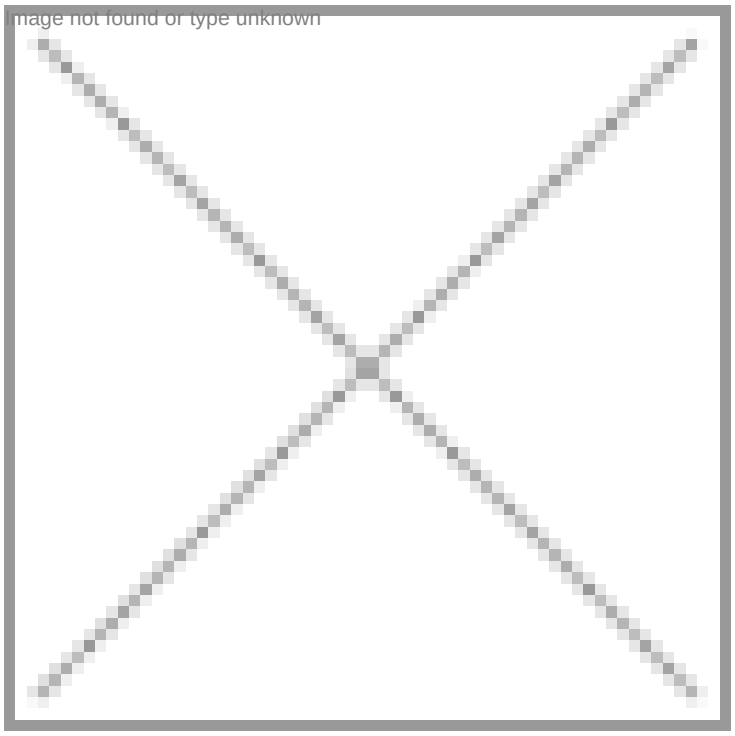
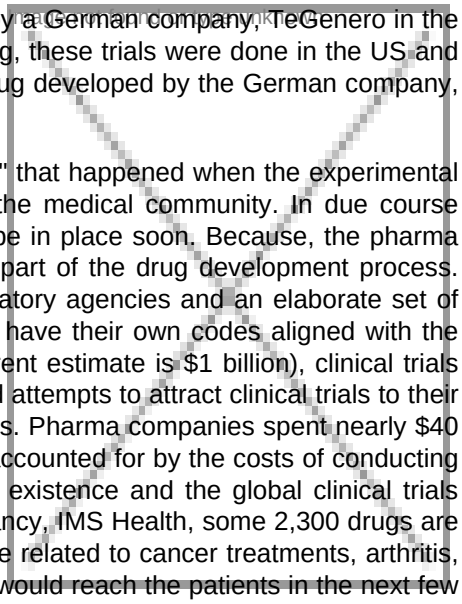


Safe Clinical Trials

Six healthy volunteers participating in the clinical trials of a bio-tech drug, developed by a German company, TeGenero in the UK last fortnight has focused global attention on the business of clinical trials. For long, these trials were done in the US and European countries. Now it is global in nature, illustrated best by these trials of the drug developed by the German company, conducted in the UK by Parexel with many of the volunteers being Asian.



Somehow, clinical trials evoke strong reactions around the world. The "adverse event" that happened when the experimental molecule TGN1412 caused unexpected reaction in healthy volunteers has baffled the medical community. In due course there will be better understanding of what went wrong and corrective measures will be in place soon. Because, the pharma and health care industry has to live with clinical trials which are now an integrated part of the drug development process. Clinical data from drugs under development is a must with most of the world's regulatory agencies and an elaborate set of guidelines governing the process. Most countries where clinical trials are conducted have their own codes aligned with the international guidelines. As drug development becomes costlier by the year (the current estimate is $1 billion), clinical trials are moving to Asian countries. India and many Asian countries are making determined attempts to attract clinical trials to their boundaries as it would benefit the health care industry to learn from these experiences. Pharma companies spent nearly $40 billion in drug development in 2005 and approximately a fourth of it ($10 billion) was accounted for by the costs of conducting clinical trials. A number of third party clinical trial service providers have come into existence and the global clinical trials market is growing by an average of 13 per cent annually. According to global consultancy, IMS Health, some 2,300 drugs are undergoing trials on human volunteers around the world now. At least 212 of them are related to cancer treatments, arthritis, viral infections and cardio vascular diseases and are in advances stages of trials and would reach the patients in the next few years.

India has been promoting itself as the "clinical trials hub" of the world. Almost all the major companies providing clinical trials have moved into the country and over 250 trials are now on in the country. The value of the clinical trials done in the country is estimated at $100 million and the industry estimates the figure to cross the $ 1 billion by 2010. India follows the international guidelines and all the stakeholders are working towards making the process stringent to avoid earning a bad name. Over 80 hospitals are currently equipped to conduct the trials according to global standards. A heated debate is likely to occur in many Asian countries which are opening up their markets for clinical trials over the adverse events in the UK. The debate should be welcome and the pharma industry too should treat this as an opportunity to stress the importance of clinical trials and the widespread benefits that accrue to the global community. This opportunity should also be used by the participating countries to evolve mechanisms to tighten any loopholes in the process that may let offending agencies off the hook. Countries should also evolve guidelines to clear some grey areas in the current process that allows the drug developer the discretion to make available the final product to the volunteers in the trials. Moral pressure should be strengthened with legal mechanism that the volunteers too become the first beneficiaries of any successful product launch for which they had played a key role.