Balancing ethics with economy in outsourced clinical trials

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Concerns are frequently raised in the pharmaceutical industry over the danger that when clinical trials are outsourced to contact research organisations (CROs), ethical protections might take a backseat to quicker and cheaper new product development. Outsourcing of trials to CROs and offshoring to developing economies, particularly in a sector fixated on driving productivity and cost reductions, emphasises the need for independent monitoring and compulsory registration.

This argument was put forward in a recent report by Dutch non-profit group SOMO (Centre for Research on Multinational Corporations), which was dismissed by some in the industry for being full of criticism and concern, but lacking in firm evidence of harm caused by lax regulatory oversight or insufficient exercise of sponsor responsibilities.

The paper slammed an "extreme" shortage of transparency among CROs and the pharmaceutical industry as a whole. As a result, the authors admitted that some of their findings "remain anecdotal and thus any generalisations … should be avoided". Accordingly, they advised interpreters of the report to view it more as a "discussion document", as opposed to conclusive evidence of the issues it seeks to address. However, it did set out a number of recommendations as to how the transparency and oversight of clinical trials in "non-traditional regions" might be improved.

As a starting point, SOMO suggested that a worldwide, compulsory clinical trial register should be set up, disclosing all parties involved in each study, including all contractors and subs. Next on its list of recommendations was an increase in the number of inspections at trial sites in so-called non-traditional areas. It was also proposed that audit results should be made publicly available with a view to achieving 100 per cent transparency.

Published in February 2011, the report stems from an observation that roughly half of all clinical trial activities are now being outsourced to CROs, with a resulting market value of approximately $24 billion (£14.7 billion) last year. And cost pressures, along with the challenges faced when recruiting for trials, are pushing an increasing number of studies into Latin American countries, China, Eastern Europe and Russia. The authors cited a number of widely-recognised commercial advantages as potential reasons for the popularity of such regions when it comes to conducting trials. These include speedy recruitment, a broad spectrum of diseases and wide availability of human resources and technical skills. At present, it is thought that between 40 and 50 per cent of new drug applications submitted in Europe and the US include trials carried out in these areas.

In addition to the growing presence of CROs in popular clinical trial destinations, large markets like India and Brazil have seen regulatory processes modified in recent times, to expedite approvals. This, SOMO claimed has been a "decisive factor" in attracting the contract research sector. It was suggested that CROs can go about their business in these regions without accreditation. "Registration at the chamber of commerce is enough to start testing drugs on humans", the authors said.

But some have argued that medical ethicists simply use reports like the one from SOMO to insinuate that

pharmaceutical companies deliberately conduct foreign trials to avoid more stringent constraints on home turf and to experiment on unsuspecting patients. Writing in the Washinton Examiner last year, two University of Chicago professors said that these concerns were "exaggerated and ignore the complexities of modern clinical research".

Thomas Philipson and Anup Malani explained that if the US Food and Drug Administration (FDA) were to push companies towards conducting more trials domestically, overseas patients would lose the "often valuable" health benefits sometimes associated with clinical research. At the same time, consumers in the US would endure slower access to new, potentially life-saving treatments, they argued.

There is certainly reason to examine the need for a balance of ethics with economies when it comes to conducting clinical trials offshore. But it seems the advantages of outsourcing experiments to non-traditional locations, which at present hold the key to that much sought-after productivity, will see the presence of CROs in developing markets continue to grow for years to come.

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