

with every facet of the viewpoints in-house. The ability of a CRO to be objective and provide constructive criticism should be considered a strength. Simple agreement with a sponsor may indicate nothing more than desperation to win the outsourcing contract.

As the pharmaceutical industry comes under greater scrutiny over its commercial activities, it must ensure that it is seen as operating ethically when carrying out clinical trials in emerging markets.¹ Since working with a CRO involves some delegation of responsibilities, companies must be sure that they work with organisations that understand the high standards required for their clinical trials.

In the major world regions for drug development, clinical trials are run to International Conference on Harmonization Good Clinical Practice (ICH GCP) standards.⁴ ICH GCP is an international ethical and scientific quality standard to ensure that clinical trials involving human participants are designed and carried out in an ethical manner. Since companies are accustomed to following ICH GCP in the major world regions, they use the same approach in emerging world regions. Yet, although ICH GCP standards would be desirable in order to generate data that are acceptable to both regulatory authorities in ICH regions and to national governments, developing countries were not involved in the development of ICH GCP and so its application in these countries should not be taken for granted, nor should it be expected.

It is imperative to pay adequate attention to informed consent procedures so potential patients understand their involvement in a clinical trial.⁴ As part of this, it may be necessary to consult with community representatives to develop innovative and effective means to communicate necessary information in a manner that is understandable to potential participants.

Potential participants should be allowed sufficient and adequate time to confer with anyone else of their own choosing to discuss the particular features of the research and to minimise the possibility that they may be subjected to undue influence or coercion. Recently, there has been considerable media coverage of clinical trials in India, with allegations that some organisations have behaved unethically when dealing with poor and illiterate patients.⁵

Working with CROs who have local experience is the best way of ensuring that clinical trials are run to the required standards worldwide. However, this does not necessarily mean working with the largest international CROs. If a company has good managers to oversee and co-ordinate the outsourcing process, they can partner with a series of niche CROs for the different markets in which they wish to conduct clinical trials.

Outlook

Pharmaceutical and biotech companies operate globally, and as they have expanded into foreign markets the importance of running local clinical trials has also grown. However, in their pursuit of commercial benefits, companies must ensure that they operate ethically. In their efforts to control the rising costs of clinical trials, most companies are now outsourcing their projects to CROs. Since it will be the CRO that oversees much of the clinical trial work in foreign markets, pharmaceutical companies must have absolute confidence in the CRO's approach as any mistakes could prove disastrous both financially and for the company's reputation. The CRO must provide value for money but also operate in a manner that maintains high standards. Only in this way can pharmaceutical companies make a success of their global R&D efforts. ■

1. Pharmbiosys, Pharmaceutical Research and Development in the 21st Century, *Pharmbiosys*, 2007. <http://www.pharmbiosys.com>

2. Brooks K, CRO Industry Update, *Contract Pharma*, 2006. <http://www.contractpharma.com>

3. Anon, CROs Usage Associated With Faster Drug Development

Speed At Comparable Quality, According To Tufts Center For The Study Of Drug Development, *Medical News Today*, 2006. <http://www.medicalnewstoday.com/medicalnews.php?newsid=36506>

4. Kermani F, Marketing and PR in Clinical Research, *Institute of Clinical Research*, 2006.

<http://www.icr-global.org/id71resources2publications.asp>

5. Barnes K, What can CROs do to keep Indian clinical trials ethical?, *Drug Researcher.com*, 2006. <http://www.drugresearcher.com/news/ng.asp?n=68154-chiltern-international-india-clinical-trial-cro>

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