Making a case for the Middle East

The cost of conducting clinical trials in the western world is growing, leading many CROs to look abroad for new opportunities. China and India are known quantities, but the Middle East remains a relatively untapped resource. **Rani Abraham** of CRO ClinTec International spoke to **Faraz Kermani** about the benefits and draw-backs of investing in this area.

During the past decade, spending on contract clinical services has been growing at an annual rate of 13.4%, with total spending in 2009 amounting to around £50 billion, according to figures in the annual Outlook report from Tufts Centre for the Study of Drug Development. To continue the growth, CROs need to constantly take advantage of possible new markets to provide competitive services for their clients as well as helping to meet ICH-GCP guidelines that require data on different ethnic populations for faster regulatory approval.

Rani Abraham is associate director, Regulatory Affairs and Clinical Operations, in the Middle East and North Africa at ClinTec and as such has experience in the workings of clinical trials in the Middle East. According to Ms Abraham clinical trial companies are looking closely at the Middle East as a place in which to invest and outsourcing in this area is on the increase: "The countries for which we have the most requests in terms of clinical trials are Saudi Arabia and Lebanon, but we are also receiving quite a few requests for Egypt and the UAE as well," she said. ClinTec has registered offices in Dubai, Egypt and the Lebanon, but it also has representatives based in all Middle Eastern countries as well as North Africa.

Jordan remains an interesting prospect, she acknowledges, having established a similar regulatory body to the US FDA, but added that ClinTec has only completed a single study there.

Companies may tend to look at the Middle East as a single geographical unit, when considering outsourcing in the area, but this is a mistake as "each of the countries has its own regulatory setup". For example, in the United Arab Emirates (UAE), a company must first apply for approval from an ethics committee. In cases where a company needs to bring a drug into the country for use in a trial, it must, following the approval, apply to the ministry of health for an import licence for an "Investigational Medicinal Product (IMP)". "This would be done as a sequential application, yet there are other countries in which you would make a parallel submission. There are still others in which you would not require ministry of health approval at all and, following the ethics committee's approval you could import the drug straight into the hospital site," Ms Abraham explained. Whereas the UAE, Egypt and Lebanon will require approval from the ministry of health for the IMP, this is not the case in the Kingdom of Saudi Arabia.

So what exactly entices a company to look at the Middle East when considering outsourcing for clinical trials? Firstly, the ICH-GCP guidelines require data on different ethnic populations in order for a drug to pass through the regulatory approval processes at a faster rate. "A drug, for example, may be effective in one ethnic population, may not have the same effect on another," Ms Abraham said. Given this emphasis on ethnicity, the Middle East is particularly good for endocrinology and neurology as well as cardiovascular, immunology and oncology studies, she explained.

On the other hand, although it could be argued that there may be only slight ethnic differences between the inhabitants of the Middle East and, perhaps, northern India, Ms Abraham argued that the less dilution of ethnicity, the more relevant a given study may be to the testing of a drug. "For example, if you need to study a drug in people of Arab descent, you do not consider any other population. However, if it is simply an observational study where genetics is not being studied, then a mixed population would be acceptable," she explained.

There is, of course, an abundance of countries in the Middle East and a CRO looking to enter this market is spoilt for choice. However, investing in some countries in the area is clearly more beneficial. "I would firstly look at the UAE, because it is very open to research at this point and a lot of proposals are coming in. I would also consider Saudi Arabia and Lebanon, which are also receiving a high number of research proposals," Ms Abraham suggested.

Dubai is a prime example of the forward-thinking Arab nations

Rani Abrahams, associate director, Regulatory Affairs and Clinical Operations for ClinTec

Many Middle Eastern countries have had a troubled political past, so stability is a key issue for CROs when they are considering investment

According to Ms Abraham Egypt was worth thinking about, principally because it is cheaper in terms of registration, with regard to establishing a presence and recruiting personnel. The regulatory structure in Egypt also appears to be reliable: "They have a body that reviews the proposals as they come in and lays down stringent regulations that need to be adhered to," she stressed. In fact, the countries that are surely candidates for outsourcing of clinical trials have a good reputation for sticking to regulations: "We as a CRO also play a role in helping them adhere to international guidelines and we actually go to the site to train the investigators, study co-ordinators and other personnel," she added. Adherence to the rules is the ethic of both foreign and regional CROs.

Furthermore, CROs tend to focus on the full range of clinical trial products, including pharmaceuticals, biotechnology products and medical devices. Although ClinTec has not been involved in many trials for medical devices they do have one currently ongoing in Saudi Arabia, Ms Abraham confirmed.

Some of the Middle Eastern countries are looking to encourage research activities by offering a certain amount of financial sponsorship. "There is for example the Sheikh Hamdan award to support medical research in the UAE, which is given to certain investigators on the basis of their trial protocol having undergone a review by the research committee," she explained. There are several awards for different trial categories. The 2009-2010 priority categories are women's health, CNS diseases and endocrine disorders.

Money is not the only consideration. Many Middle Eastern countries have had a troubled political past, so stability is a key issue for CROs when they are considering investment. But despite "Lebanon having come through a few wars", it has "in fact been in the news with regard to how well clinical trials have been conducted there," Ms Abraham commented. She added that with regard to political stability in other countries in the area, ClinTec had not been negatively impacted.

Regarding the recruitment of clinical trial subjects, there have been suggestions that the Middle East is an attractive place for clinical trials because the population is relatively clinically naïve. However, Ms Abraham pointed out that "Not only are some international study documents translated into Arabic, but also the country-specific information may be required to be included in the informed consent form", which is required by all approving ethics committees. Patients generally understand the form and would not be enrolled otherwise.

There are, of course, cultural differences to Western nations that CROs would be well advised to take on board when considering the Middle East. "I would say that in the months of July and August as well as in Ramadan [the traditional month for fasting with a time of occurrence that varies year-on-year] things tend to slow down a bit. It is so hot here that many of the people leave the country and go abroad on holiday. Meetings are often postponed and take place at a later time as well," Ms Abraham explained. During Ramadan, as a general rule, people tend to work shorter hours due to fasting. During 2009, it fell during the month of September and so the slow-down over the summer was simply extended.

Overall, the Middle East is therefore proving to be a fertile ground for the growth of clinical trials and CROs can expect relative stability and encouraging financial support. With reliable regulatory systems, low outsourcing costs and willing trial participants, the area is worth serious consideration, despite the intense heat. ■