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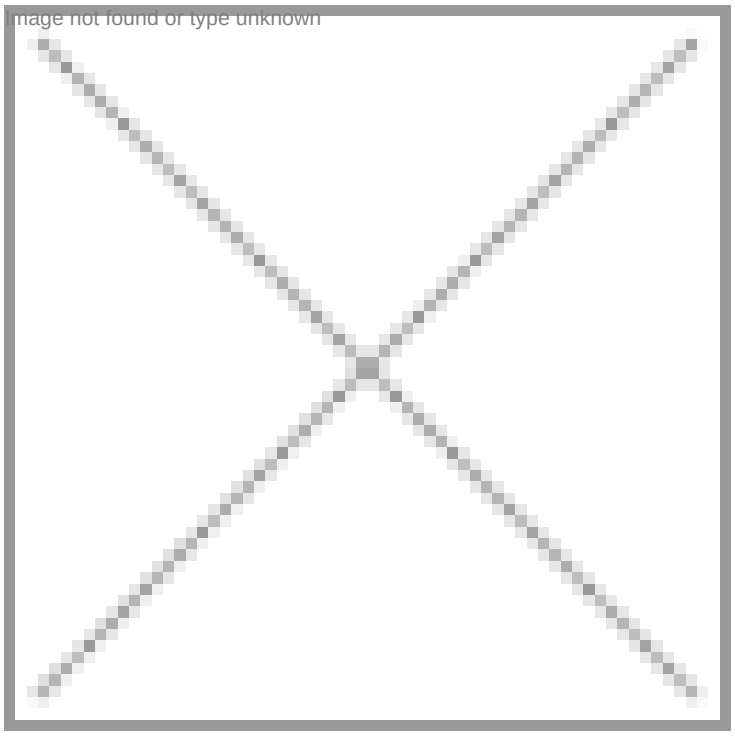
'Collaboration with local CROs is a good strategy'

04 October 2007 | News



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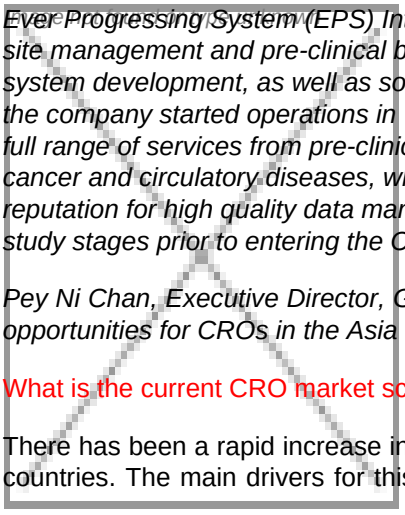
-Pey Ni Chan, Executive Director, Global Business Development, EPS



Ever Progressing System (EPS) International, a leading Japanese CRO is primarily involved in activities like clinical research, site management and pre-clinical businesses. EPS provides staffing service, pharmaceutical- and medical-information system development, as well as software development and CRO services in China, SouthEast Asia, and Oceania. Recently, the company started operations in Taiwan. With growing market trends, EPS has established a structure which can provide a full range of services from pre-clinical study to post-marketing study. It offers long-term and large-scale studies in the areas of cancer and circulatory diseases, which are among the top three causes of death in Japan. Moreover, it has developed a reputation for high quality data management because of its involvement in software development relating to the pre-clinical study stages prior to entering the CRO business.

Pey Ni Chan, Executive Director, Global Business Development, EPS International, shares her views with BioSpectrum about opportunities for CROs in the Asia Pacific region. Excerpts of the interview:

What is the current CRO market scenario in Asia Pacific region?

There has been a rapid increase in the outsourcing of clinical trials in the Asia Pacific region especially in key Asian emerging countries. The main drivers for this increase are cost, speed, regulatory infrastructure and commercial value involved in the

CRO market. In addition, the acceptance of the clinical trial data by the US FDA for pivotal studies from Asian countries has been encouraging.

What advantages do the key Asian countries have for conducting clinical trials?

The key advantages for conducting clinical trials in the region include regulatory support, capacities and capabilities and finally low operating costs. The operating costs include fees for IRB and regulatory purposes, site professional fees, patient study cost, site start up costs, logistic costs and so on. In terms of capacities, the key Asian countries have most experienced investigators who are trained in the US and Europe and have actively participated in the international clinical research and publications. These countries have good clinical research centers that provide dedicated research coordinators to support all trial activities. Besides, they also have the presence of major global, regional and local CROs, central laboratories and clinical suppliers. In terms of capabilities, these countries have good patient compliance, availability of standard treatment modalities and availability of diverse patient groups and also follow international medical practices.

What are the challenges that the CROs are facing in the region?

Different regions are facing different issues. It is not necessary that all countries in the region should have the same issue. The key challenges, in Japan, Korea, and Taiwan include English language, differences in local and cultural practices and accessibility of regulatory and IRB information. In addition to these, Japan has other issues such as patient recruitment and obtaining informed consent from the patients. However, this is not a major area of concern in Singapore and Hong Kong. Availability of patient pool is a key challenge as far as Singapore is considered.

According to you, what strategies can help CROs overcome these challenges?

It is necessary to have strong local clinical operations team with bilingual ability. Second strategy could be entering into collaboration or working with the local CROs who have good track record. And the third could be conducting comprehensive feasibility studies to meet the global clinical development strategy and timeline.

Narayan Kulkarni