

## **Industry-Sponsored Clinical Research in Malaysia: New Chapter in 2011**

According to the Economic Transformation Programme Roadmap, Malaysia only averages 100 clinical trials per year, which is a mere fraction of what Taiwan, a country similar in population size to Malaysia is doing. This is in spite of Malaysia's large multi-ethnic patient population with unique biometric identifier, good healthcare infrastructure, nationwide network of local Clinical Research Centres (CRCs), large numbers of highly trained/experienced healthcare workforce and established disease registries. It is indeed surprising that with such an ideal environment for clinical research, Malaysia is not achieving more.

As recently indicated in *Clinical Trial Magnifier*, a journal dedicated to clinical research activities, Malaysia is one of the emerging regions for clinical research which should be able to attract at least 300 trials per year. Malaysia was the highlight of *Clinical Trial Magnifier's* June issue which featured a series of articles on the country's clinical trial performance and potential. Article 1 discussed Malaysia's healthcare and clinical research infrastructure; the country's strengths and weaknesses were also mentioned here. The challenges as outlined in the article include ensuring fair contract and transparent financial transactions, lack of clinical research awareness among potential Ministry of Health investigators, regulatory and ethics review timelines and the need for better support in business development, contract and budgeting,

financial administration, site personnel and other resources at investigative sites.

In the 2nd article, the number of industry-sponsored clinical trials in Malaysian between 2008 and 2009 was measured according to application information submitted to the Ministry of Health's Institutional Review Board (IRB). This IRB reviews mostly applications from investigators from the government hospitals and clinics. Each major medical university and some of the private hospitals have their own IRBs. The authors of this article believed, that with a strong clinical research infrastructure, the number of clinical trials in Malaysia will increase 8-fold and total revenue to be generated is estimated at US\$136.6 million.

The Malaysian government had a similar perception of clinical trial industry as potential economy driver. By giving it more precedence, 2011 will bring a string of changes. Some of these changes have been thought of as ambitious or even ambiguous. But in reality, these were not decisions that were rashly made as the strategies are based on in depth research and analysis of the existing clinical research environment. One major transformation in the horizon is the corporatisation of the Clinical Research Centre's contract research unit. Known as the One Stop Centre (OSC), this division was set up several years ago to provide a single point of contact and facilitate industry's access to investigators

and patients for industry sponsored clinical research (also known as contract research). The OSC provides infrastructure and practical plan to support professional and efficient clinical trials. This model has been found effective, but in order to cater to more than just Ministry of Health facilities, it needs to be transformed to be a corporatised entity. It will still be 100% government owned like the Health Tourism Council and Health Promotion Board. In addition to managing contract research, this business entity (which will be known as Clinical Research Malaysia), will do marketing and business development, hiring and retaining of industry 'talents', partner commercial contract research organisations/site management organisations, etc.

The CRM also aims to meet industry expectations of speedy ethical approvals, outperform rivals in patient recruitment and improve data quality, support and logistical services. Finally it will coordinate the promotion of Malaysia as a high quality and high performing clinical research site in the ASEAN region.

As the Economic Transformation Programme brings Malaysia closer to achieve its 2020 vision, we need to bear in mind that there is only ten years left for this major economic overhaul. But as contract research has been identified as 'quick wins', which means it can be achieved within a relatively short amount of time because it need moderate involvement from the private sector, it seems that we are on track. Nevertheless, despite needing only moderate private sector involvement, just like any economic endeavors, collaboration is vital as the government will not

be able to do it on its own. The investigators and the industry play crucial roles; without their full commitment and cooperation, the dream of Malaysia as a conducive environment for clinical research will remain a dream.

More on CRM and the future of contract research in Malaysia in our next issue.

**Resources:**

1. Economic Transformation Programme: A Roadmap for Malaysia. Creating Wealth Through Excellence in Healthcare. pp 552–587.
2. Goh PP *et al.* A Case Study: Refining Clinical Research Infrastructure Clinical Trial Magnifier 2010; 3: 203–218.