Interview with Pik Pin Goh, Director, CRC â?? Center for Clinical Research

16.02.2011

Tags:

CRC â?? Center for Clinical Research

Malaysia has good ethnic diversity, cost-effective infrastructure, and highly qualified principal investigators (PIs) and these elements have been in place for a long time. Why is now is the right time for a drive forward in clinical trials?

Dr. Goh Pik Pin (GPP): Malaysia does offer a strong base for clinical trials. As you say, Malaysia benefits from strong ethnic diversity within its population which sets it apart from many other countries in terms of clinical trials. The quality of the facilities and investigators is also very high. In addition, doctors speak English and every doctor must have a Good Clinical Practice (GCP) qualification before they can begin working on trials. Malaysiaâ??s trial timelines are also better than those in China, India, Philippines. All these factors stand the country in good stead when attracting international Contract Research Organisations (CROs).

Malaysia also has unrealised potential for clinical trials, because there are a sizeable number of patients still untapped. Whereas Singapore has a population of fewer than 5 million Malaysia benefits from a population approaching 28 million and therefore there are many more patients for clinical trial recruitment.

The reason that this is the right time for clinical trials in Malaysia is that they now benefit from a clear government commitment. The Prime minister has launched the countryâ??s Economic Transformation Programme last year October where contract research has been identified as one of the Entry Point Projects. and would like to attract foreign investors to contribute to this development.

The Ministry of Health has also expanded the number of specialist hospitals and increased the number of specialists who are capable of conducting clinical research. At CRC, we have identified some of the hospitals with strong track-records in clinical trials and the government is now channelling resources into these hospitals. The government is therefore active in promoting better research in Malaysia, expanding the CRC network of hospitals and the number of investigators. Consequentially, this is an exciting year for clinical trials in Malaysia.

What would you say were some of the limitations of conducting clinical trials here?

GPP: I think there are two limitations. The first of these is the hiring and firing of staff. The government has its own methods of recruiting and it is often difficult to hire new staff because of the salary scales. Experienced workforce in this industry therefore prefers to work in the private sector rather than in government hospitals.

The second element is the financial constriction. In contract research there is need for monitoring in terms of investigator fees. We therefore hope with this initiative we can overcome these restrictions.

Loh Choon Shane (LCS): Essentially, it is a drive for transparency in the financial management of clinical trials.

The global CRO industry represents around $20 billion and the Ministry of Health aims to expand the number of clinical trials in Malaysia 10-times by 2020. What are the CRCâ??s key performance indicators?

LCS: Above all, CRCâ??s main KPI is to increase the number of clinical trials. Apart from that it is also to drive FDI through international CROs operating in Malaysia. There are currently 10 international CROs in Malaysia and we expect this number to grow in line with 2020 targets. More CROs will mean more clinical trials and a significant step closer to the 10â??fold increase in clinical trials in Malaysia by 2020.

Clearly, companies will not invest in Malaysia if they do not see a return on investment. Out of the 10 CROs operating in Malaysia there are currently 4 who have only home-base CRA. They conduct trials in Malaysia but are currently evaluating how Malaysia performs. The inherent strengths of Malaysia as a clinical trial destination should encourage these CROs to eventually establish a centre here. When they see that Malaysia has strong potential in key therapeutic areas such as cardiology and oncology then they will invest in Malaysia.

How have the initiatives of the Clinical Research Centre contributed to encouraging the development of clinical trials in Malaysia?

GPP: Over the last 10 years the CRC has established patient registry databases. The CRC is often told that we are the only country with such well-established data resources in this region. Along with fast recruitment these registries make Malaysia extremely attractive for foreign companies. Latter phase clinical trials involve observations of a large number of patients and we have these resources already available.

According to the World Health Organisation, Malaysia stands out from other countries because of the compulsory nature of research registration. Indeed, any research conducted by the Ministry of Health or in government hospitals needs to be registered. The CRC has just conducted a meeting with industry and the universities where we urged them to register their sites within this national register. The Director General of health and the Minister of Higher education have sent a letter to the deans to tell them to register their respective universities. We hope that one day soon we can truly refer to a national register.

The information that we have accumulated for clinical trials will also include other elements. We are looking to include adverse events monitoring in this register and also a register for medical publications. The National Medical Research Register (NMRR) is almost all public access with directories covering investigators and the trials. The NMRR is also linked directly to the ethics committee. Through this interactive element, expedited approval can be achieved using this site as well as Clinical Trial Agreement (CTA) approval updates. The overall effect is to increase the speed of response for the applicant.

LCS: However it must be noted that within this drive to promote the clinical trial industry the CRC will never allow the Malaysian population to end up as simply guinea pigs for medical science. Over the years there have of course been a number of controversies concerning poorer countries and unethical clinical trials. Malaysia will not join this list.

The benefits of attracting clinical trials are still focused around patient care. Naturally, the CRC wants doctors to excel in their clinical services, knowledge and patient care, and become KOLs for their respective therapeutic areas. CRC promotes and encourages research to our doctors. Through the conduct of global multi-centred trials, our doctors will be networking with internationally renowned peers and learning and exchanging information about practices from other countries, have access to new knowledge, latest innovations and discoveries through the international research scene. Exposure through such a platform will also contribute to the development of KOLs among our participating doctors.

In 2007 DG of Health Tan Sri Dr Ismail Merican lamented that sponsors were neglecting Malaysia to focus on China, India, for phase 3 and 4 and Singapore for phase 1 and 2. What is Malaysiaâ??s focus for clinical trials?

GPP: Although we are exploring options for early phases, Malaysiaâ??s focus will remain phase 3 and 4 trials. The main therapeutic areas of focus are cardiovascular, oncology, hepatology â?? 8% of the population have hepatitis B and consequentially many trials are conducted in this area â?? alongside mental health, and rheumatology. Within these therapeutic areas Malaysia has many key opinion leaders (KOL), indeed we are internationally renowned for our KOLs. For example, we have consultants including cardiologists in Sarawak who are widely known and respected in the industry.

Albert Liou of Parexel said that one of the advantages of international CROs were that they were able to offer sponsors a region-wide network of clinical trials. Do you feel that such a thing as a clinical trials hub can exist in this globalised industry?

GPP: Within Asia there are a few countries such as Taiwan, with an aspiration to be a hub for clinical trials. However, I agree with the premise that clinical trials are more of an international affair today. The pharmaceutical companies are mostly based in the USA and Europe. Trials are therefore coming from American and European pharmaceutical and biotech sponsors who are interested in conducting clinical trials across the region. Malaysia would like to be one of the core destinations within this regional network.

Within this picture Malaysia is partnering with other countries including Thailand and Korea in developing clinical trials. Malaysia is relatively new in the field of clinical trials and needs to work with more established clinical trial destinations in order to choose the right path.

There are conflicting accounts of patient recruitment in Asia: some highlighting the regionâ??s strengths, others saying that Asian patients are more wary of subjecting themselves to medical science. How would you evaluate patient recruitment in Malaysia?

GPP: Recruitment is often largely dependent on the success of the principal investigators and study coordinators. It depends on the areas and experience of the investigator. Patients themselves are becoming more and more aware of clinical trials and in certain areas where patients do not have access to drugs for example they are more willing to enrol in trials. Put simply, when patients have good trustworthy doctors and are in need of new therapies they are more willing to subject themselves to trials.

Fortunately, Malaysia has responsible doctors who do not participate in trials for the sake of it. Their emphasis is always patient care and furthermore, the ethics committee acts as a strong gate keeper of patient safety. The system is in place to maximise good outcomes for the patient and ensure that we obtain the best trials.

In terms of CRCs work, we are looking to establish a public awareness programme to foster greater awareness about clinical trials. There is some misconstrued views which states that we are using

patients and are not putting their interests first. The doctor patient ratio is quite tight and waiting times are still quite long. Therefore it is stated that doctors should not be devoting themselves to clinical trials when patients on the waiting list have unmet needs. This misapprehension needs to be addressed.

What would you like to say about the ambitions of CRC and what people can expect from the organisation?

GPP: The CRC is the clinical research arm of the government and the Ministry of Health. The Centre collaborates with the University of Malaya Medical Centre, the Clinical Investigation Centre and the Universiti Sains Malaysia. These are also contributing to developing clinical trials in Malaysia. We aim to build more hospitals with good investigators. All of these sites will become centres of excellence for clinical trials and we will build a team including pharmacists and doctors and related professions to answer this countryâ??s call for clinical trials to be a National Key Economic Area.

LCS: We are looking at the patientsâ?? needs and the doctorsâ?? needs to further their research. It is not just about money but about furthering patient care. These two elements must be held in balance with the revenue generation from clinical trials.

See more interviews