Akhmal Yusof â?? CEO, Clinical Research Malaysia (CRM)

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Dr Akhmal Yusof, CEO of CRM sheds light on the capacity for all stages of clinical research in Malaysia. He discusses the importance of human resources for the countryâ??s research future and explains what makes Malaysia such a worthwhile location to invest in international clinical research.

Could you give our international readers an introduction to the scope of CRMâ??s operations?

CRM was created by the Ministry of Health of Malaysia in 2012 to increase the level of sponsored clinical research conducted in Malaysia. If we consider the level of sponsored clinical research per capita, Taiwan and Hong Kong are conducting three to four times the level of research as Malaysia, so we have significant scope for growth.

We have five key strategic areas of operations. Firstly, we familiarise our doctors with conducting studies and ensure they are GCP (Good Clinical Practice) accredited. Secondly, we assist research sites in fulfilling all necessary requirements of the prospective sponsored clinical research. Thirdly, we collaborate closely with clinical research stakeholders, which includes the sponsors, regulatory authorities, ethics committees and national agencies. While under the Ministry of Health, we also work with players from across the universities and private sectors including pharmaceutical/research industry. This enables us to pool ideas and find the best way to advance. It is also important to know issues that other stakeholders face, for example the challenges pharma is encountering when trying to conduct research in Malaysia. Next, we aim to raise the public awareness of CRM and specifically clinical research. Thus, we are very active on all social media platforms as well as in national & international conferences. Finally, we invest in human capital to create careers in clinical research.

Our aim is for all our study coordinators: doctors, nurses, and bio science graduates, to have the ability to build a career in clinical research. We do not want them to be coerced into other fields due to economic reasons. We want them to stay in the areas where they are passionate and pursue their interests further. We have grown by over 150 percent since 2012. We began with a team of around 75 people, now we have 165 employees, and will reach 179 by the end of the year. This is because there are now 850 new and ongoing researches which need study coordinators in multiple sites. My team is undertaking the site resource management for these researches over 500 sites.

What is it about Malaysia that makes it a good place to host clinical researches?

We have a population of 32 million which represents a third of the worldâ??s genomics. To understand how pharmacokinetics works in these populations, a research will require an adequate pool of patients, which Malaysia can provide. When they are looking at the effects of certain conditions on minority groups, it is thus very beneficial to conduct such studies in Malaysia. Moreover, Kuala Lumpur is home to the biggest hospital in Southeast Asia â?? Hospital Kuala Lumpur. It has more than 2,000 beds and over 6,000 health care personnel work there. In Malaysia, there are several hospitals of a similar size. Hence, there is a huge pool of patients within a diverse range of therapeutic areas.

Secondly, we have a good command of English so there is no need for documents to be translated. This cuts bureaucracy and increases the accuracy of administration. Thirdly, the common diseases in Malaysia are the similar in the western populations.

Finally, we work very hard in maintaining timelines. The timeline to review clinical researches in the country has been reduced tremendously. The ethics review committee under the Ministry of Health now sits twice a month, helping us to complete the review of these study proposals at Ministry of Health sites within six to eight weeks. Moreover, reports have shown that the timeline could be cut further down to 31 days in the case of no issues. Considering reduced timelines in ethics and regulatory review, Malaysia is now one of the most efficient places in the region to conduct research.

How do you attract the stakeholders to bring the multi-national companies to Malaysia?

To attract the studies to Malaysia, we must be good at three things. Our first requirement is that we must maintain our short timelines. Secondly, we must be reliable in recruiting the number of research patients required. The final point is the most significant as it touches upon the quality of the data garnered for research. Since we are aiming to prove safety and efficacy of new treatments, data must be quality-compliant and adhere to protocol. It is by maintaining that quality that we attract not only the largest MNCs but also the new upcoming biotech companies.

What is the potential at this time to create infrastructure for early stage clinical research in Malaysia?

Currently, Malaysia lacks exposure on the world stage for its involvement in early stage researches, as the number we conduct is still small. Thus, we are working with centres in Malaysia to develop their capacity for phase I or pre-clinical researches. This is part of the Ministry of Healthâ??s plan to develop early stage researches.

Indeed, all research centres, namely hospitals, are being equipped for early phase development. Standard operating procedures are currently being developed to fulfil regulatory requirements for site accreditation. CRM has provided resources to improve facilities and infrastructure at these sites. Finally, we have created a risk management system. We need to have good communication and manage risks well so that when things go wrong, we can manage the situation effectively.

In conjunction with this, we are ensuring that our researchers have the appropriate training to conduct early stage researches. We are sending medical professionals on scholarships to train in centres that have conducted a large number of early phase researches, for example Kings College London and the Christie, Manchester. Moreover, the country has formed a scientific review panel to support our ethics committee in performing scientific evaluation of phase I studies. Experts in the field of pharmacology, toxicology, and scientists having conducted phase I studies abroad are

participating in the panel in the aim to review first-in-human studies, so that if a study is suggested, it is properly vetted to ensure that it can be conducted safely in Malaysia.

One of your mandates is to conduct feasibility studies in Malaysia. What are the main stumbling blocks that prevent some clinical researches from being brought to Malaysia?

One of the challenges is in meeting the recruitment target set. This we have noted is due to overpromising in number of targeted research patients at the initial stage due to limited information/ data source. Taking note of this, CRM has begun working closely with the Ministry of Health for access to the Malaysian Health Data Warehouse (MyHDW) to ensure a more accurate data representation in targeted recruitment number.

The other challenge is attracting patients to join clinical research. This is why we are running the â??I Am AWAREâ?• campaign nationwide which provides the public with a true view of clinical researches. There is a stereotype that clinical research is only an experimentation when it should be seen as a potential treatment for the patient.

We have heard from others in the industry that there is a worry of a brain drain in Malaysia. How do you overcome this to ensure that you recruit the best people?

The brain drain in Malaysia is a challenge that we face, and part of the solution will require changes to our government policy. From our perspective, we are invited by national talent management agency to speak with doctors abroad and present to them the opportunities that are available in Malaysia. In my view, clinical research is one of the areas which could encourage our Malaysian talents to return. We also invest heavily in training our staff so that they have the talent and skills to achieve great things if they cross over to international and local companies. A number of our former staff have moved on to Boston Scientific, Novo Nordisk, PPD, Johnson-Johnson, MSD and even organisations like DNDi. Consequently, the calibre of research team that we produce is of high standard.

It is also encouraging that the Ministry of Health has emphasised that research is part of their key performance index for government doctors. Consequently, they can undertake clinical researches as part of their career.

In addition, there is an advantage of global recognition. The more studies conducted in Malaysia, the greater the recognition and acknowledgement that we can do the job properly and effectively. If we consistently make doctors part of the authorship of the studies, they will develop their skills and become world recognised, and will want to be part of research at home in Malaysia.

Digitalization has become a key theme for the new Malaysian government. How do you see greater digitalization benefiting clinical researches?

Digitalization will be a positive step. Perhaps in the future the patient will no longer have to go to the doctor to partake in the research. For instance, there are companies that have medical devices that can be synchronised with smartphones, measuring heart beat and ECG which could be sent directly to the medical professional. Thus, studies could be conducted remotely, with patients only having to go to the hospital once, which would be considerably easier for them. Digitalization will also mean

that there will be a wealth of data in terms of research: how the patient is improving in relation to standard therapy, and how the patient is faring against the new therapy.

What are the key priorities for CRM in the next four years?

We are in the final stages of ISO9001:2015 accreditation, currently completed internal audit. In November, we will begin the improvement plan, and by late November, the external auditing will begin. We are on track to obtain accreditation by the first quarter of 2019. Many of our personnel are located across Malaysia with only 30 people working in our headquarters. Thus, we need to have standard operating procedures which would ensure consistency on the quality of our studies across the country. Gaining recognition in international standards would strengthen our position as a globally trusted research organisation. This means that we may be moving towards consultancy, providing services to other nations around the region to conduct research. This is how we believe that we are able to develop new business opportunities.

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