

Clinical Research Malaysia (CRM) â?? Dr. Mohamed Ali Abu Bakar, CEO



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Clinical Research Malaysiaâ??s CEO discusses the need for Malaysia to focus on high quality pivotal trials rather than simply on a high number of trials. He shares with us the encouraging progress of Malaysia as an attractive place for trials since clinical research was placed under the healthcare NKEA National Key Economic Area program implemented in 2010.

Malaysia has a natural advantage over many other countries as a center for clinical research. Why is Malaysia still remaining in the shadow of its neighboring country Singapore?

Our infrastructure in Malaysia to conduct clinical trials is on par with Singapore and both public and private hospitals have been investing in the latest equipment to ensure that Malaysia is an attractive place to conduct trials.

In order to do proper clinical research, a country must first have a very robust regulatory framework and secondly ensure the highest ethics and transparency, which include patient safety. The challenge also is that many MNCs so far have seen Malaysia as a pass through rather than a stable place to conduct clinical research. This is unfortunate, since Malaysia has a high number and wide range of clinical facilities available and the government through the economic transformation program has added considerable value and exposure to clinical trials in Malaysia. We just need to change the perception of Malaysia as only a tourism destination, into a sophisticated, highly business oriented and advanced healthcare market where companies can invest to carry out high quality clinical trials.

In 2013, the MOH announced that NCDs were the largest cause of hospital admission, mortality and premature death in Malaysia. Therefore, the need to develop a high number of clinical trials is critical. What is your view on this issue?

NCDs are a consequence of changing lifestyles and cultural habits but they are also a result of genetic predisposition. In Malaysia, both of these factors play a consequent role and because many ethnicities (Chinese, Indians, and Malaysians) are present here, it creates the perfect pool and test platform to conduct high quality yet affordable trials.

According to statistics provided by PEMANDU, over 300 clinical trials have been carried out last year. Besides the good performance on the number of trials, what should still be accomplished?

Today 460 clinical trials are being performed in Malaysia, and since the implementation of the healthcare NKEA program, the number of clinical trials has been exceeding expectations year after year.

It is true that Malaysia must not only perform high number of trials, it must above all be able to conduct high quality trials. In order for Malaysia to take the next step, we have to focus on exceeding expectations and delivering to our partners and clients flawless results in the shortest period of time.

For clinical trial success, it is crucial to have a wide access to investigators (doctors) as well as patients. What challenges have you come across to pursue both ends?

Malaysia has a relatively high number of doctors, but finding a large numbers of doctors does not influence the quality side of trials. As of today, Malaysia must still improve in terms of quality in comparison to other Asian powerhouses like Singapore or Taiwan. To do so, we need to find, train and equip quality doctors and specialists. Therefore we have been collaborating with international organizations to improve the overall quality of our trials, and we have also implemented a program called "Mentor Mentee" to grow the pool of potential investigators by linking younger specialists to experienced investigators.

Fast patient recruitment is another key area for Malaysia, as we have a wide pool of patients available and the investigators are capable of recruiting them in a shorter amount of time than other countries in Asia. For a pharma company, each day that is saved from developing a new drug and putting it on a market is an important revenue gain. At CRM, if we can convince these companies that we are capable of reducing this timeline and also conduct high quality trials, we will succeed and attract a lot of companies.

What needs to be done to help Malaysia become a clinical hub?

Primarily, we need more specialists. Most doctors here are generalists and until we manage to have a large enough pool of excellent doctors in highly specialized scientific areas it will be challenging to compete on the clinical international scene. Therefore proper training and follow up needs to be implemented. We also need to create a system where everyone is connected and shares the same vision "transforming Malaysia into a fast track high quality clinical territory. Finally, we need to coordinate well with the government and PEMANDU, to find common grounds and work towards the same vision. Since clinical trials are highly regulated, governmental support is fundamental to our endeavors.

Could you tell us more about the clinical landscape in Malaysia and how it compares to Singapore?

Most companies invest in phases two to four in Malaysia, and among the main CROs (Quintiles, Parexel, INC, Novotech, Icon, PPD) in the world, 90 percent of them have offices in Malaysia. Quintiles is one of CRM's strategic collaborators and we are working with several CROs to assess how we can collaborate and find common grounds to produce high quality pivotal trials (trials

which change the way you manage a disease). The idea here is not to overpromise results and embark ourselves in too many projects. We only want to deliver quality results and help Malaysia raise its footprint on the international scene as an attractive place for pivotal trials. Cardiology is one area where we excel, even though not many trials have been performed here, but once again the idea is quality over quantity.

It is important from an economic and competitive point of view to specialize and be excellent in certain phases rather than be average from drug discovery to phase four. Historically Phase 1 trials have been located in Western Europe and the US and Singapore has slowly been catching up. To become a key player in drug discovery, a country must develop an entire "ecosystem" to support the drug development process, but this is complex and costly to develop. Malaysia should therefore remain focused on phase two to four, but at the same time start to improve its capabilities in Phase I studies.

What can we expect for the future development of clinical research in Malaysia?

Malaysia needs to develop a new focus on patient recruitment services and attract specialized companies in that area, to remain an attractive place to companies wishing to have access to a wide and diversified pool of patients.

Our goal is to have 1,000 trials by 2020, but more importantly, we want the world to know that Malaysia has the capacity to perform pivotal trials. If stakeholders around the world realize that a new disease is cured because of a study performed here, the repercussions will be immense. With a well-established regulatory framework and a committed government placing clinical research as a national priority, we can be confident for the future of Malaysia as a top class destination for clinical research.

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