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Malaysia to build on its clinical research potential

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Malaysia's aspiration is to be a developed nation by the year 2020. With 10 years more to prepare for this anticipated year, current Prime Minister Datuk Seri Mohd Najib Tun Razak announced that the country will undergo a major economic transformation, with revamp planned for 12 national key economic areas. These changes, when implemented, will help the country emerge as a strong economic competitor in just a few years. One of the key projects involve creating a supportive ecosystem for the growth of clinical research, and this article will give an update on the modifications outlined for this industry under the Malaysian Economic Transformation Programme.

Clinical research comes under healthcare, which has five other economic projects: 1) mandating private health insurance for foreign workers; 2) pursuing generics export opportunities; 3) reinvigorating health travel through better customer experience, proactive alliances and niche marketing; 4) creating a diagnostic services nexus to achieve scale in telemedicine for eventual international outsourcing; and 5) developing a health metropolis- a world-class campus for healthcare and bioscience. Of the six projects, clinical research was categorised as a quick-win project, which means it is ready for immediate implementation. The only other quick-win project under healthcare is the private health insurance for foreign workers.

Malaysia's performance in clinical research is good but all relevant stakeholders believe that the country has better potential. Although Malaysia has the right attractions, the country has to reshape the entire spectrum of its industry before it can be a favourable spot for clinical research activities in the region. And to do this, the Economic Transformation Programme for clinical research has included the following ten strategies:

1) Transform the Ministry of Health's contract research unit: The ministry's clinical research center incorporates a unit for contract research (a one-stop center). With economic transformation in place, this unit will be corporatized to improve coordination of the industry-sponsored clinical research industry in Malaysia. To ensure financial transparency, this corporatized entity, known as Clinical Research Malaysia (CRM), will act as the clearing house for funds. It will also be the

center for business development, training and marketing. Moreover, all other strategies will be implemented through CRM.

2) Increase clinical research sites in the Ministry of Health, university and private hospitals. Malaysia has over 300 hospitals that can serve as trial sites.

3) Create a pool of investigators and site coordinators. This will be done by addressing the lack of research culture and finding ways to incorporate protected time to conduct research within the healthcare system and the allocation of time for training.

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4) Tap a large pool of patients. In 2009, Malaysia reported more than 45 million outpatient treatments and over three million hospital admissions. Such numbers would enable this multi-ethnic nation of 28 million people to outdo its competitors in terms of patient recruitment.

5) Optimize ethics and regulatory processes

6) Attract more international and local sponsors. The CRM will encourage international pharmaceutical companies to conduct trials in Malaysia.

7) Increase contract research organizations (CROs) and site management organizations. Malaysia will especially support local CROs that focus on lifestyle diseases, such as diabetes, cardiovascular disease and tropical infectious diseases.

8) Build Malaysia's reputation as a clinical trial hub. The CRM will conduct marketing campaigns, both locally and internationally, employ local and regional experts as consultants and maintain a database of excellent trial sites.

9) Expand the scope of trials. Malaysia has established itself with a good track record for phase III/IV trials. It is now gearing to take on earlier phase studies, especially phase I trials.

10) Facilitate bioavailability and bioequivalence development.