

# Contract Research at MOH Hospitals



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The global contract research industry for new drug development has achieved an annual growth rate of 15% to reach more than US\$20bil in 2009. The Tufts Outlook Report in 2007 had projected up to 65% of FDA-regulated industry-sponsored trials conducted outside of the US a few years later. These emerging markets include Asia, as the growth in this region has outpaced the global market with an annual 30% growth to reach US\$1.6bil. Malaysia's performance, however, has lagged behind its Asian peers, with a mere annual growth of 7-8% (2003-2009). Currently, it is performing below its capacity with 116 industry-sponsored trials conducted over 2008 and 2009, with a total of 406 study sites (average of 3.5 sites per trial).

The IMD World Competitiveness list for 2009 ranks Malaysia as among the top six Asian countries together with Japan, China, South Korea, Taiwan and Singapore. It is also among the top 40 countries in the world, in terms of gross expenditure for research and development (GERD), or 0.64% of the Gross Domestic Product (GDP). Clinical research is an untapped potential. To capitalise on this, Malaysia needs to create a supportive ecosystem to grow clinical research, especially focusing on quality and speed that industrial sponsors look for in deciding upon



the preferred location for industry-sponsored clinical trials. A special task force in the government has thus identified the contract research industry as one of the National Key Economic Areas (NKEAs) in the Economic Transformation Programme.

Malaysia's strength is in its single information and referral system for government hospitals. The network of 20 local Clinical Research Centres (CRCs) nationwide provides Malaysia the opportunity to develop more new sites for clinical research. Other advantages

include the multi ethnic population with unique biometric identifier, comprehensive patient registries in major therapeutic areas and supportive regulatory environment. Malaysia has nine international contract research organisations (CROs) operating in its shores and four local CROs. The country has 138 secondary and tertiary Ministry of Health (MOH) hospitals that service over 15 million patients in various therapeutic areas, which has generated about 175 active investigators. This is merely a fraction of the approximately 2800 specialists at MOH facilities (in total there are 5000 specialists from both the public and private sectors). The goal is to galvanise these strengths and transform this industry by creating a supportive and complete ecosystem to multiply the number of clinical trials conducted in the country from about 100 trials in 2009 to a target of 1000 in 2020. This would generate a financial impact of GNI of US\$134mil and 1000 job opportunities.

To achieve this, a comprehensive plan of action and strategies was put in place. Firstly, the contract research arm of the CRC will be corporatised to enhance coordination and create business development opportunities. **The CRC will gradually shift its task of facilitating commercial trials to this corporatised entity, and will continue to cultivate a research culture among healthcare providers at MOH facilities by facilitating and promoting investigator-initiated trials and other clinical research.** The MOH will act as an enabler to fast-track clinical trial registration and ethics review and allocate space for clinical research in MOH hospitals with CRC units. The Malaysian government will fund the initial capital expense of \$12mil to establish Clinical Research Hubs at 9 CRC networks to be centres of excellence for contract research (they are Penang, Perak, Selayang, Ampang, Serdang, Putrajaya, Kuala Lumpur, Sabah and Sarawak) between 2011 and 2013. These centres of excellence will emphasise healthcare service, research and training; which will also complement health travel, local pharma and medical technology industries. The programme is expected to be self-funding from 2014 onwards. This corporatised entity, which shall be known as Clinical Research Malaysia or CRM is non-profit but will acquire a fraction of the institutional fees paid by sponsors to fund its support services. A part of the fee will be used to fund the training of investigators. The government will also be responsible for directives to enhance and encourage trials in Malaysia as well as for policies and procedural changes to facilitate contract research in public, private and academic facilities.

This ambitious initiative of CRM which will be run as a business entity and the CRC, MOH and the

Malaysian government will act as enablers, are based on feedback from the local CROs, global CROs and pharmaceutical companies. Indeed, a concerted effort through the following strategies is needed to grow Malaysia's clinical research ecosystem to achieve its goal of 1000 trials per year by 2020:

1. Increase sites in the MOH, private medical institutions and universities.
2. Expand the pool of investigators and study coordinators.
3. Tap into a larger pool of patients.
4. Optimise ethics and regulatory processes to shorten ethics and regulatory review timeline.
5. Attract more international and local sponsors.
6. Grow the number of contract research organisations especially to have several home-grown, globally successful CROs who serve both the domestic and international markets and improve site management.
7. Transform CRC's contract research arm into a business entity to attract, facilitate, and enable trials to deliver both speed and quality.
8. Provide services along the entire spectrum of drug/device development, including Phase 1 trials and analytical studies.
9. Facilitate bioavailability & bioequivalence development.
10. Build Malaysia's reputation as clinical trial hub.

In summary, this NKEA project will consist of i) transforming CRC's contract research arm into a business entity; ii) developing the human capital base by galvanising local investigators, site coordinators and clinical research associates, enhancing their capability with training and increasing support by providing the investigators with protected time and trained research staff on site; iii) optimising the process and systems by building Malaysia's reputation for speed and quality, by streamlining and strengthening ethical and regulatory submission and approvals [currently the timeline from submission of application to its approval is 2 to 3 months as compared to Singapore at 1 to 1.5 months, Taiwan at 2 to 3.5 months and Thailand at 4 to 4.5 months]; iv) building a resource base for clinical research through the establishment of the 13 state Clinical Research Hubs and nine centres of excellence. **M**

*This article is also co-authored by Ms Loh Choon Shane, Clinical Research Centre, Hospital Kuala Lumpur.*