

## Working with Clinical Research Malaysia to Move Malaysia Forward

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The Malaysian government has committed funding to improve the healthcare systems in order to further support clinical research. Clinical Research Malaysia (CRM) is a non-profit organization - wholly owned by the government of Malaysia, which intends develop infrastructure for Clinical Research Centre networks, and be able to support global industry sponsored research (ISR) requirements. Recently, CRM appointed a new CEO, Dr Akhmal Yusof, who held individual meetings with various industry sponsors and CROs to promote the services provided by CRM. George Clinical Malaysia (GCM) was one of the CROs invited to participate. In addition to this, Dr Yusof met with MOH investigators and institution directors to promote clinical research, as well as discuss ways to improve facilities and resources available to conduct clinical research.

To date, Malaysia has 66 ISR trial sites which have been approved by the Ministry of Health (MOH) and consists of an amalgamation of public and private hospitals. To date, they have participated in over 1000 ISR trials. By the end of 2014, 202 new ISR trials were approved by the institutional review board (IRB). CRM targets 230 new trials for 2015, and their vision for 2020 is to conduct 1000 ongoing trials in Malaysia.

George Clinical Malaysia met with Dr Yusof and discussed initiating improvements to the site contracting process – in particular improving ethics approval timelines, which is currently one of the most time consuming hurdles for site start up. In order to alleviate this situation, CRM is in discussion with their legal officers along with the MOH legal to update a bipartite clinical trial agreement (CTA) template for MOH sites. In addition, Malaysia recently introduced a goods and services tax (GST) which has affected the CTA and budget; however CRM has developed a CTA addendum for this GST clause. George Clinical Malaysia also suggested to CRM to construct a comprehensive database on patient populations for dedicated therapeutic areas for all MOH sites. This database will facilitate feasibilities and reduce start up timelines, as well as attract industry.

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One of Malaysia's key hurdles is also the lack of quality of resources in comparison to international standards. In order to address this, CRM have introduced Good Clinical Practice (GCP) workshops to train additional MOH investigators and Site Coordinators (SC) in conjunction with introducing a mentor-mentee program for experienced Principal Investigators (PIs) to coach young investigators. George Clinical Malaysia actively works with PIs to share information on these trainings to new investigators or unexperienced SC. As a result of this, sponsors and CROs will gain a greater sense of assurance that Malaysia possesses the necessary skills which can conduct their varied clinical trials while delivering a service of high quality.

### About George Clinical Malaysia

George Clinical Malaysia was established in 2009 and since then has consistently delivered on some of our largest programs. Based in Kuala Lumpur, George Clinical Malaysia also covers neighbouring South East Asian countries such as Singapore and Indonesia. We have established networks of cardiovascular, diabetes and renal Investigators in this multi-racial country which has significant investments into raising its profile as a clinical research destination.