

**SPEECH BY YB DATO' SRI LIOW TIONG LAI  
MINISTER OF HEALTH MALAYSIA**

**AT THE OPENING OF THE 5<sup>th</sup> NATIONAL CONFERENCE FOR CLINICAL  
RESEARCH 2011 (NCCR 2011) & LAUNCH OF CLINICAL RESEARCH  
MALAYSIA (CRM)**

**SUNWAY PYRAMID CONVENTION CENTRE  
PETALING JAYA, SELANGOR, 22 JUN 2011**

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Dr Goh Pik Pin,  
Director, Network of Clinical Research Centres,  
Ministry of Health, Malaysia.

Distinguished guests, ladies and gentlemen,

Good morning and *Salam 1 Malaysia*.

1. First and foremost, allow me to thank the Organizing Committee for inviting me to officiate at today's historic, dual events. The first is the opening of the 5<sup>th</sup> National Conference for Clinical Research 2011 with the theme, "Trials, Registries And Databases: Many Angles, One Aim." The second is the launch of Clinical Research Malaysia (CRM) that will function as a non-profit, governmental, site management organization to attract clinical trials to Malaysia by facilitating access to the country's extensive network of clinical research centres.

**The Clinical Research Route to Healthcare Transformation**

2. As you are aware, Clinical Research has been identified as one of the Entry Point Projects under the country's National Key Economic Area (NKEA) for Healthcare, which would bring both economic benefits and improved well being for the *rakyat*.

3. There are compelling reasons for the Ministry of Health to focus on clinical research as an entry point project. It would be a natural progression for the Ministry, as clinical research has already been identified as a key growth engine

under the objectives of the 10th Malaysia Plan. This places it under the radar of the government's Economic Transformation Programme (ETP) towards developed nation status. After much brainstorming with key stakeholders that included pharmaceutical industry representatives, the 1,000-person workshop and the 2-month-long Lab ultimately identified clinical research as an entry point project due to our existing strengths.

4. Since the setting up of our Clinical Research Centre in 1999, we already have in place comprehensive patient registries in major therapeutic areas, Good Clinical Practice (GCP)-certified investigators and a reliable Centralised Institutional Review Board. State Research Committees are being established in all the 13 states nationwide, entrusted with the task of promoting and strengthening the clinical research culture and ensuring support within the healthcare system.

5. In addition, the Ministry has 23 tertiary hospitals that are already linked within the Network of Clinical Research Centres. This network continues to be expanded with the upgrading of facilities and strengthening of human capital, ICT and other research-related resources.

6. Within this extensive network, the Ministry has identified nine hospitals to be designated as Centres of Research Excellence (CoRE) by therapeutic areas, each led by a Key Opinion Leader who will train and mentor doctors and nurses in clinical research. These CoRE hospitals are: Sarawak General Hospital in Kuching, Sarawak; Queen Elizabeth Hospital in Kota Kinabalu, Sabah; Tengku Bainun Hospital in Ipoh, Perak; Penang Hospital in Penang; the Serdang, Selayang and Ampang Hospitals in Selangor; and the Putrajaya and Kuala Lumpur Hospitals in the Federal Territories.

7. Of course, this is only one side of the story. In Malaysia, Clinical Research is also a forte of the teaching medical institutions. We also understand that we need enablers besides patients – we need a good regulatory platform, where certain

initiatives suggested by the Pemandu Lab will be fast tracked, such as the GCP and GLP (Good Laboratory Practice) inspection and monitoring program and mutual recognition among ASEAN regulators. On top of that, investment incentives have been provided via the Malaysian Biotech Corp for those who want to set up Contract Research Organisation (CRO) operation in Malaysia.

### **Launch of Clinical Research Malaysia**

8. Today we are launching Clinical Research Malaysia (CRM) as a national effort to provide a unique entry point to the Ministry's network of 23 clinical research centres (CRCs) which are in turn linked to other CRCs established in private hospitals and medical universities. CRM will function as a not-for-profit, governmental, site management organization that will be the single, information and referral entry point to our extensive network of 341 hospitals and hundreds of clinical trial sites.

9. CRM will source for potential investigators and assist in GCP training needs. I am happy to inform that in 2010 alone, nearly 1,000 clinicians, pharmacists, nurses, clinical research associates, study coordinators and support personnel were GCP-certified.

10. Also, CRM will focus on ways for Malaysia to be a bigger player in the globalisation and off-shoring of contract research, by ensuring transparency in financial processes, reducing timelines and a single marketing platform. This will mean working closely with the pharmaceutical, biotechnology and Clinical Research Organisations to come to Malaysia for their clinical trial outsourcing needs and to eventually set up operations in Malaysia.

11. CRM will be guided by a taskforce whose members comprise representatives from Clinical Research Organisations, pharmaceutical associations, biotechnology corporations, universities, Association of Private Hospitals, the CoRE hospitals and the Society for Clinical Research Professionals. In addition,

CRM will strive to engage the public so that they are comfortable with the knowledge that clinical research is in their best interest.

### **Transforming Healthcare**

12. The forward looking policies on the proper conduct of research, put in place by the Ministry of Health, has placed Malaysia firmly on the right track to follow the roadmap outlined by the ETP in achieving the goals of the NKEA.

13. As tracked by the National Medical Research Register (NMRR), there has been much interest generated in clinical research, with 581 research protocols registered from 2008 to 2010. Of these, 374 (64%) were investigator-initiated research (IIR) and 207 (36%) were industry-sponsored research (ISR). The number of ongoing ISR is 164 with 70 new trials as of May 31, making a total of 234 ISR. We hope that after this launch, the number will grow each year until we reach our target of 1,000 clinical trials by 2020.

14. As the aim under this Entry Point Project is to increase foreign direct investments (FDI) through a higher number of ISR projects that matter to our patients, the Ministry is speeding up the process of transforming the ecosystem in support of clinical research.

15. To achieve this target, CRM's priorities will be to get more clinicians, nurses and study coordinators to be GCP-trained, improve efficiency in the approval procedures, upgrade on-site facilities and be more aggressive in marketing and promotions.

16. In Asia, Malaysia was ranked by the A.T. Kearney Global Services Location Index (GSLI) 2011 as the third most attractive off-shoring destination after India and China, based on its Financial Attractiveness, People Skills & Availability, and Business Environment. This will boost our chances of attracting more Foreign Direct Investments (FDI) from international Contract Research Organisations (CROs).

17. We currently have 13 CROs and we hope to increase this number as we approach 2020. One of the success stories is that of Info Kinetics, the first local Malaysian CRO that is also the first to conduct a Phase I study in Malaysia. I understand that within the last 10 years, they have gained various international accolades.

18. Under the ETP, Malaysia is moving away from being a net importer, by transforming the ecosystem to be an attractive clinical trial outsourcing destination to tap into the RM 422 billion global pharmaceuticals industry.

19. The recently announced Digital Malaysia Master Plan will have a positive impact on the ICT-powered data management required by patient registries, healthcare databases and performance measurements. As reflected by the NCCR 2011 conference theme, “clinical research from many angles; all for the one aim of achieving clinical excellence”.

20. Finally, I would like to congratulate the Organising Committee chaired by the CRC Director, Dr Goh Pik Pin, for successfully holding this conference for the fifth year. This has contributed greatly towards increasing awareness of the importance of clinical research.

21. On that note, ladies and gentlemen, I have pleasure in declaring open the 5<sup>th</sup> National Conference for Clinical Research 2011. It also gives me great pleasure to officially launch Clinical Research Malaysia. Thank you.