

National Conference for Clinical Research 09
9-10 July 2009; G Hotel, Penang
Keynote address: Clinical Research in Malaysia
Yg Bhg Tan Sri Dato' Seri Dr Hj Mohd Ismail Merican
Director General of Health Malaysia

Assalamualaikum Warahmatullahi Wabarakatuh and good morning distinguished guests. Thank you for joining us today. As always, when I talk about clinical research, I can't help feeling nostalgic and excited. Nostalgic because I remembered the initial struggle I had, to set up the CRC and excited to observe the tremendous leaps Malaysia has taken in clinical research, through the network of CRCs and I must commend all those who have made this happen and the list include the present DDG (R & TS), Dato Dr Maimunah Abdul Hamid, the Director of CRC, Dr Lim Teck Onn and all the other directors of the Network of CRCs throughout Malaysia.

As you can glean from the media coverage, we in the MOH have our hands full dealing with the global health-related crisis of H1N1, not to mention local threats such as dengue fever and haze-related illnesses. Still, I will always make time for clinical research, something I have always been interested in, personally and professionally.

Today is indeed a proud day for all of us who conduct and manage clinical research in Malaysia a judging by the attendance today, there are quite a lot of us in the category. We have healthcare professionals, people from the industry, GLCs and others. Many have come from outside Malaysia to share their expertise and experience. Many are acknowledged experts in their respective fields of interest. I would like to welcome all of you for making time to come here.

National Conference for Clinical Research 09
9-10 July 2009; G Hotel, Penang
Keynote address: Clinical Research in Malaysia
Yg Bhg Tan Sri Dato' Seri Dr Hj Mohd Ismail Merican
Director General of Health Malaysia

Research and Development is important, if we wish to realise national health, social and economic goals. The Ministry of Health recognises this. That is why we position research as one of our key strategies to develop the health sector in Malaysia. We believe in enhancing research and development to support evidence-based decision making.

Ladies and gentlemen,

We have to grapple with health threats and crises every day. Some are big and others are not so big. We must be ready to face crises and deal with them effectively and expeditiously. Risk communication is the key. You either make it or break it. Often, you have to handle more than one crises at the same time. You have to handle people including politicians, healthcare professionals and the public. If we don't things handle well, from one crisis we may end up with another crisis.

To aspire confidence and trust, it would help if we were to base our decisions on scientific evidence. It would help if we scurry and rush into the labs to conduct research without someone else telling us that doing research at times like this is good and strategic. New diseases are about new understanding and also new questions- the what, the why, the where, the how and the which. Our researchers must ignite the fire of excitement in themselves. True researchers will do that. Do

National Conference for Clinical Research 09
9-10 July 2009; G Hotel, Penang
Keynote address: Clinical Research in Malaysia
Yg Bhg Tan Sri Dato' Seri Dr Hj Mohd Ismail Merican
Director General of Health Malaysia

not wait for someone to tell us that 'now is the time'. We as seasoned researchers must know when an opportunity arises. Only then can we make a difference.

I am encouraged by the presence of so many big names in the field of clinical research. Some of you have come from far to share your expertise and experience and for that I would like to thank you and wish you well.

I also acknowledge the respective deans and professors of clinical research from the academic universities who are here to deliver their lectures. Their presence at this National Conference for Clinical Research is a very positive sign that the local universities will continue to collaborate and cooperate in clinical research. I just hope they can move in tandem with the MOH in spearheading clinical research so that we can be a global player. Being the best on the local front may not amount to much if others do not know of your existence. We must not just put labels on our institutions to say we are good at what we do. We must deliver and the time to deliver is now. It has been said that 'time waits for no man'. We can also say that the big global researchers and industry players will not wait for mediocre Malaysian researchers. It is a competitive world we live in. do not expect handouts, excel in what we do and the rewards will come pouring.

National Conference for Clinical Research 09
9-10 July 2009; G Hotel, Penang
Keynote address: Clinical Research in Malaysia
Yg Bhg Tan Sri Dato' Seri Dr Hj Mohd Ismail Merican
Director General of Health Malaysia

Ladies and gentlemen,

For the next two days, we leave our regular work and busy schedules to be here with the hope of learning and sharing; aligned with the theme of *Expanding the Range of Clinical Research in Malaysia*. Although healthcare will always be our priority and treating patients will always remain a doctor's primary task, clinical research is important and always relevant. This is because clinical research focuses on prevention, diagnosis and treatment of diseases. It also involves the testing of medicines, newer procedures or interventions and medical devices for use and application in clinical settings.

Ladies and gentlemen,

As we challenge ourselves to improve diagnostic and treatment methods, we need to be mindful that every finding, no matter how minor or how unexpected, will contribute to the business of saving lives, improving the quality of life or reducing disease burdens. Patient safety must of course never be compromised under any circumstances and that is why we have strict ethical committees that painstakingly examine all procedures and proposals as well as actively monitor all requests for clinical research.

To ensure strict and ethical research, all investigators and parties involved in clinical research need to adhere to the Malaysian Guidelines for Good Clinical

National Conference for Clinical Research 09
9-10 July 2009; G Hotel, Penang
Keynote address: Clinical Research in Malaysia
Yg Bhg Tan Sri Dato' Seri Dr Hj Mohd Ismail Merican
Director General of Health Malaysia

Practice. Here, we have also specified several local modifications from international guidelines, to suit our cultural and legal specifications. Investigators too have to be GCP trained and certified. This is where the National Committee for Clinical Research, of which I chair, comes in. This committee is responsible for coordinating and promoting clinical research in Malaysia and the members are not only from the MOH. We also have representatives from universities, organisations and the industry. My Deputy-Director for Research and Technical Support, Dato Dr Maimunah will provide more insight on these topics in her plenary talk tomorrow morning.

Ladies and gentlemen,

CRC is constantly striving to promote and support clinical research in Malaysia. While much of this work is undertaken by the pharma and biotech industry usually on a contract basis, it is CRC's firm conviction that Malaysian investigators are capable of conducting original work too.

CRC along with many local investigators have published numerous research papers in which a few has gained entry into reputable international journals like the American Heart Journal and Nephrology. We are already witnessing an escalation of investigator initiated trials (IIT) with well over 17 trials that have been initiated since 2008 in collaboration with CRC, MOH and other international institutions.

National Conference for Clinical Research 09
9-10 July 2009; G Hotel, Penang
Keynote address: Clinical Research in Malaysia
Yg Bhg Tan Sri Dato' Seri Dr Hj Mohd Ismail Merican
Director General of Health Malaysia

We wish to improve Malaysia's contribution to the evidence-based therapeutics, particularly in areas relevant to our population's health. Our present contribution in this is sadly negligible, given the dearth of clinical trial publications from Malaysia.

The investigator-initiated trials program was launched specifically to provide practical help to investigators to initiate clinical trials. CRC is at your service to provide the much needed assistance in the technical aspect of conducting a trial in terms of compliance to applicable regulatory guidelines, obtaining ethical approval, trial design and protocol development and pharmacovigilance amongst other things. So far we have 7 ongoing trials that are MOH funded and our MOH sites are participating in 10 internationally funded investigator initiated trials. The official launch of the IVRS Central randomization service later this morning will further lend support to the accepted competence of local investigators.

Through the Ministry of Health, CRC also ensures that yearly grants are made available for these investigator trials, so please make full use of this facility. I believe that given the right supporting environment, our Malaysian investigators would definitely be able to rise to the challenge and contribute to the ever changing field of medicine and research.

The MOH through the NIH encourages research which supports health services; (we encourage networking and linkages between component institutes of the NIH and also with other research agencies, within and outside the country).

National Conference for Clinical Research 09
9-10 July 2009; G Hotel, Penang
Keynote address: Clinical Research in Malaysia
Yg Bhg Tan Sri Dato' Seri Dr Hj Mohd Ismail Merican
Director General of Health Malaysia

NIH also encourage use of research in health management so that programmes and research activities are needs driven and cost effective, through priority setting, resource allocation and development of facilities and human resources that are effective and systematic; and produce new discoveries to strengthen and develop health systems and health technologies which are up to date.

Ladies and gentlemen,

The Ministry of Health of Malaysia recognises the critical role that the pharmaceutical industry plays in the country's healthcare system. This is reflected in the rapidly growing pharmaceutical market in Malaysia. In addition to a strong global presence with representation from all of the major international drug companies, the local pharmaceutical industry has seen tremendous growth and increasing market share.

Our local companies have ventured beyond our shores and are doing well in countries across the region. Although the development of the industry is still in its infancy, the future trend seems promising. The Clinical Research Centre (CRC), as the clinical research arm of the Ministry of Health, (and by extension, the lead agency of the government of Malaysia) will play an instrumental role in advocating the vision to make Malaysia as the region's preferred clinical trial destination.

National Conference for Clinical Research 09
9-10 July 2009; G Hotel, Penang
Keynote address: Clinical Research in Malaysia
Yg Bhg Tan Sri Dato' Seri Dr Hj Mohd Ismail Merican
Director General of Health Malaysia

With such promising times before us, it is critical for those of us in the healthcare sector, to continuously strive to ensure that Malaysia emerges as a strong contender in the pharmaceutical and therapeutics sector, as well as in medical and diagnostic biotechnology. This is particularly relevant for the people involved in clinical research such as the local investigators, industry players and regulatory agencies. The gathering of these local and regional experts in meetings such as this would open up opportunities for networking and exchange of ideas.

Ladies and gentlemen,

I am convinced of the valuable returns and meaningful results that clinical research will bring to our doctors and our country. I am particularly proud that the Ministry's Clinical Research Centre, which was a mere glimmer of an idea I had more than 10 years ago, has been embraced by major public hospitals across the country. Malaysia is truly unique, because no other country has such an integrated and comprehensive network that offers nationwide access to investigator and patients.

Seventeen clinical research centres, at least one in every state, is surely a major achievement for CRC. I am informed that all the heads and representatives for the 17 CRCs had a management meeting here, just before this conference, their six

National Conference for Clinical Research 09
9-10 July 2009; G Hotel, Penang
Keynote address: Clinical Research in Malaysia
Yg Bhg Tan Sri Dato' Seri Dr Hj Mohd Ismail Merican
Director General of Health Malaysia

months progress report and review of plans. The CRCs have also been submitting regular monthly progress reports on their KPIs of research and publications.

Ladies and gentlemen,

I officially launched the One Stop Centre for the network of CRCs here in Penang just two years ago. This 'call centre' provides a single point of contact to access all our investigators in the MOH as well as other hospitals. From the reports I received, I am happy with the response and reception of the industry to our initiative.

In 2008, there were a total of 98 feasibility studies conducted for 28 separate clients, and we approached a total of 1896 investigators. More importantly, the OSC has been able to achieve industry standard turn-around time and at the same time extended the number of available investigators.

Beyond just feasibility, I am happy to note that we are able to capture and report figures of trials done with the National Medical Register (NMRR). In 2008, we had a total of 87 industry trials in 323 sites with 5400 patients' recruitment. This year up to June 30th, we have 47 trials in 241 sites with 3,800 patients' recruitment. As such we are on target to surpass last year's achievements.

National Conference for Clinical Research 09
9-10 July 2009; G Hotel, Penang
Keynote address: Clinical Research in Malaysia
Yg Bhg Tan Sri Dato' Seri Dr Hj Mohd Ismail Merican
Director General of Health Malaysia

Ladies and gentlemen,

As CRC continues to expand its network, it works towards contributing to the development of the contract research outsourcing market by promoting Malaysia as clinical trial hub and by facilitating the industry as well as the development of human resources.

CRC has been working with the Malaysian Biotech Corporation to conduct Good Clinical Practice (GCP) workshops throughout the country. Last year, a total of 18 courses were conducted and we have almost five hundred extra GCP certified investigators.

The network of ministry hospitals and clinics is our unique advantage as it establishes our public healthcare system as a good potential to identify clinical investigative sites that are appropriately equipped and qualified investigators to meet study requirements. Of course, the ease in accessibility would not mean much, if these hospitals do not perform or fulfil the criteria of being capable clinical trial sites. Malaysia has to back up its claims with evidence and I can confidently say that we have accomplished this.

Our past results have indicated that, throughout the years, we have achieved high recruitment rates in many major global clinical trials. We have also established ourselves in several therapeutic areas such as psychiatry, cardiology, diabetes, haematology and hepatology.

National Conference for Clinical Research 09
9-10 July 2009; G Hotel, Penang
Keynote address: Clinical Research in Malaysia
Yg Bhg Tan Sri Dato' Seri Dr Hj Mohd Ismail Merican
Director General of Health Malaysia

We are all aware that there is a large potential for economic development and foreign investment. Clinical research can be touted as one of our economic drivers and may even complement the health tourism sector. Working in centres of excellence and being recognised by their peers in their clinical field will attract doctors across borders to refer patients. Thus we should consider promoting clinical research and inculcate the desire to publish in all our clinicians. This will support our drive to place Malaysia as a premier referral centre among patients and doctors.

Ladies and gentlemen,

Some might question the benefits or even the need for clinical research. However, one has to recognise that modern medicine is evidence based and we would not be able to progress unless we discover and prove new therapies that are more effective. Without medical research, our profession and patient would still be subject to outdated treatments and drugs. In this modern era, cutting edge clinical research avails our patients of the latest drugs and our physicians keep themselves updated on the latest progress in their respective fields.

As such, Malaysia, to diversify and develop our growing clinical research industry, is moving towards establishing early clinical development units in the country. Although we have had some basic early phase 1 trials, these are only for bio-

National Conference for Clinical Research 09
9-10 July 2009; G Hotel, Penang
Keynote address: Clinical Research in Malaysia
Yg Bhg Tan Sri Dato' Seri Dr Hj Mohd Ismail Merican
Director General of Health Malaysia

equivalence and bio-availability. We need to move up the value chain, and position Malaysia for the next phase of our clinical research development.

We are looking to place this facility in Ampang Hospital and we will be ready to partner industry to establish a facility within the next few months. We have identified foreign partners who will provide knowledge transfer and create new employment prospects for our science graduates in this exciting field.

The early clinical development facilities and the related technical and regulatory procedures and experience, represents an opportunity for Malaysia to emerge as a choice location for early clinical development studies in Asia.

Malaysia already has the trained human resources and modern medical infrastructure to support the development of dedicated early clinical development facility. These advantages are well complemented with a strict regulatory and ethical oversight to ensure the well-being and safety of human volunteers participating in these trials.

Ladies and gentlemen,

Another of our Ministry of Health's strength's is our established patient registries. So far we have 30; each one targeting different therapeutic areas. Data from these registries can be used to discover the natural history of diseases and to evaluate

National Conference for Clinical Research 09
9-10 July 2009; G Hotel, Penang
Keynote address: Clinical Research in Malaysia
Yg Bhg Tan Sri Dato' Seri Dr Hj Mohd Ismail Merican
Director General of Health Malaysia

access to and quality healthcare for these diseases. Beyond clinical effectiveness, registry may also be designed to collect resource use and cost data for the same patients to be used in modelling cost effectiveness. Furthermore, efficacy in a clinical trial for a well-defined population may not necessary be generalizable to the Malaysian population and a locally-based patient registry is crucial. The registry is also particularly useful for tracking effectiveness outcomes for a longer time period than is typically feasible with clinical trials.

All stakeholders in healthcare can benefit from patient registry data: clinicians demanding more resources to better treat their patients; academic organisations out to implement treatment guidelines; payers looking out for better value for their money; and drug or device manufacturers to meet their pharmaco vigilance or device surveillance obligations.

Ladies and Gentlemen,

The trend has moved to research being registered and approved online. For example, in May 2007, the World Health Organization International Clinical Trial Registry Platform (WHO ICTRP) was launched with the aim of having a global trial registration system. In Malaysia, the National Medical Research Register (NMRR) is the medium that evaluates online research submission to the appropriate authority for approval and online review of submitted research by

National Conference for Clinical Research 09
9-10 July 2009; G Hotel, Penang
Keynote address: Clinical Research in Malaysia
Yg Bhg Tan Sri Dato' Seri Dr Hj Mohd Ismail Merican
Director General of Health Malaysia

relevant appointed reviewers. Currently, NMRR is used by all our National Institutes Health especially, CRC. The NMRR was developed to ensure research transparency and to increase public trust in the conduct of medical research.

Since its initiation, 308 clinical trials has been registered on the NMRR and submitted for approval. Over 4,000 investigators are registered in NMRR where 70 % are MOH personnel while 15% come from the private sector. MOH personnel conducting clinical research are required to register, but I urge clinical researchers from the universities and private hospitals to do so also. NMRR also enables online submission for MOH research grants and approval for publication. We are now planning to introduce electronic notification to the Clinical Research and Compliance Section, National Pharmaceutical Control Bureau (NPCB) via NMRR. This will apply to all drugs trials that are conducted in Malaysia, not just those involving MOH sites.

Ladies and gentlemen,

Another important element in the whole process of drug discovery and development is non-clinical safety studies. The Ministry of Health is aware that non-clinical safety done in Malaysia has not been accepted in many developed countries, as the data generated must be compliant with Good Laboratory Practice (GLP). Hence, such guidelines are needed and subsequent compliance to the adopted GLP by all the parties involved is required.

National Conference for Clinical Research 09
9-10 July 2009; G Hotel, Penang
Keynote address: Clinical Research in Malaysia
Yg Bhg Tan Sri Dato' Seri Dr Hj Mohd Ismail Merican
Director General of Health Malaysia

Since the Ministry of Health has always been committed to help potential enterprises tap the opportunities in drug development research, we have taken initiatives to make Malaysia as member of the Non-Organisation for Economic Co-operation and Development (OECD) that adheres to the Mutual Acceptance Data (MAD). Only then, will test data generated in Malaysia be accepted in all OECD countries and other nations adhering to this MAD system. This will then enable companies to gain better access to markets and business opportunities in all 30 OECD countries, which when combined, currently produce 60% of the world's goods and services.

Malaysia is a Provisional Member to this OECD MAD system since October 2008. This is, however, only an initial step as Malaysia needs to completely adhere to the OECD MAD system, for non-clinical safety data generated in Malaysia to be accepted by OECD countries and other adhering economies. Efforts are made by the Ministry of Health through the National Pharmaceutical Control Bureau (NPCB) which had been designated as the Compliance Monitoring Authority (CMA) for the non-clinical safety testing of test items contained in pharmaceutical products, cosmetics products, veterinary drugs and food additives to establish its GLP Compliance Monitoring Programme.

Similar efforts had also been taken by the Department of Standards (STANDARDS MALAYSIA) of the Ministry of Science, Technology and Innovation. Department of Standards is the other designated CMA for the non-clinical safety testing of test items contained in industrial chemicals, pesticides,

National Conference for Clinical Research 09
9-10 July 2009; G Hotel, Penang
Keynote address: Clinical Research in Malaysia
Yg Bhg Tan Sri Dato' Seri Dr Hj Mohd Ismail Merican
Director General of Health Malaysia

feed additives, and biotechnology (non-pharmaceuticals). Ideally, Test Facilities/Laboratories should also play their role in making Malaysia fully adherent to the MAD system by taking steps to ensure Test Facilities and non-clinical safety studies conducted are GLP compliant and in accordance to OECD standards.

Since the Ministry of Health Malaysia has been designated as the coordinator for the GLP Compliance Monitoring Programme for Malaysia, I am taking this opportunity to launch the Malaysian GLP Compliance Programme which is steered by NPCB and STANDARDS MALAYSIA. Therefore, we are looking forward and would like to invite Test Facilities/ Laboratories which are ready to request for verification of compliance to Principles of GLP from these two CMAs.

Ladies and gentlemen,

We have the means, resources, expertise and support system.

Therefore, I urge us to utilise the resources we already have and seek out new opportunities. Let us emulate other Asian countries such as Japan, China, India, and Singapore and develop our nation's capacity. This is the time for building scientific and academic partnerships and expanding existing collaborations.

This year, Malaysia was a first time participant at the 45th Annual Drug Information Association Conference held last month in San Diego. Despite this being our first participation in this global showpiece for pharmaceutical development, we received many interested visitors and potential clients. Many of

National Conference for Clinical Research 09
9-10 July 2009; G Hotel, Penang
Keynote address: Clinical Research in Malaysia
Yg Bhg Tan Sri Dato' Seri Dr Hj Mohd Ismail Merican
Director General of Health Malaysia

the visitors were pleasantly surprised and delighted to discover a possible destination for their clinical trials. I do hope many of these initial enquires will develop into actual projects.

Ladies and gentlemen,

The task at hand will not be easy. It requires hard work, dedication and passion. Nevertheless, you will have the backing of the Ministry of Health and we will try our best to provide all the assistance you need in your clinical research endeavours.

Last but not least, let me extend my congratulations to the organisers; Associates of Clinical Research Professional Malaysia (ACRPM) and the Clinical Research Society of Penang (CRiSP), for bringing together professionals from all areas in clinical research and for ensuring a smooth and well-planned event. Surely to successfully put together such a grand endeavour is something very commendable. I also express gratitude to the sponsors for their active cooperation and generous contribution.

I appreciate all your hard work in making this conference a reality. With big-scale events such as this, investors and shareholders would develop a growing interest in Malaysia's potential in clinical research and its related industries.

To the faculty, participants and delegates; thank you for being part of the congress and I believe you will benefit from the programme that have been prepared. Most importantly, I trust you would utilise the knowledge gained here, in your respective

National Conference for Clinical Research 09
9-10 July 2009; G Hotel, Penang
Keynote address: Clinical Research in Malaysia
Yg Bhg Tan Sri Dato' Seri Dr Hj Mohd Ismail Merican
Director General of Health Malaysia

hospitals or institutions. Knowledge is power, but the power you possess will be futile if it is not translated into research applications.

For all our foreign visitors, I wish you a pleasant stay and hope that you will bring back fond memories of this meeting. While you are here, do take the time to visit our beautiful country. Have an enjoyable and fruitful conference.

I hereby officially declare the 3rd National Conference for Clinical Research 2009 open.

Thank you.