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Keynote Address by Director-General of Health Tan Sri Datuk Dr. Mohd Ismail Merican at the Launch of the National Conference on Clinical Research (NCCR) on 26 October 2007.

CLINICAL RESEARCH IN MALAYSIA: PAST, PRESENT AND FUTURE

I am sure that many of you here are still in a festive mood this morning, so I take this opportunity to wish you Selamat Hari Raya!

In recent years, we have seen tremendous growth in the clinical research undertaken in the National Institutes of Health, in particular the Clinical Research Centre in its effort to improve patientsô outcomes through quality and ethical clinical research.

When I say clinical research, I am referring to the kind of research that finds better ways to prevent, diagnose or treat diseases and disorders, test new medicines or devices or to learn about health problems.

This is only to be expected of the Ministry of Health as the leading healthcare provider in the country with 137 general and district hospitals, the Ministryôs goal is to undertake quality and innovative research that is focused on improving peopleôs lives.

When I speak of innovation, it is only to be expected that the MOH should be at the forefront of clinical research to devise new and better ways to diagnose medical conditions, treat patients, perform procedures or develop breakthrough treatments.

Clinicians need to take advantage of the Ministryôs facilities to forge medical innovations, introduce better ways of advancing clinical research while raising our standards of patient care without compromising on their safety.

PAST

Ladies and gentlemen,

In the past, clinical research was a fragmented activity in the Ministry were ñcottage industryò types with small projects conducted by clinicians with the interest, commitment and perseverance in research.

There was minimal government grant funding for medical research and few industry sponsored clinical trials as clinicians were not trial savvy and the GCP (Good Clinical Practice) was a foreign word.

The majority of clinical trials then were uncontrolled Phase IV marketing studies, or "seeding" trials, largely funded and managed by local/regional marketing offices to help promote the use of recently registered drugs among local doctors.

At the time we already realised there was a growing trend to conduct clinical trials in developing countries and Malaysia needed to implement GCP guidelines as part of their regulation of clinical trials.

The Clinical Research and Compliance Section of the National Pharmaceutical Control Bureau plays an increasingly important role in issuing the Clinical Trial Import License (CTIL) and ensuring compliance with GCP and Good Laboratory Practices (GLP).

Early on, the obvious benefit of GCP is acknowledged by Malaysia's Drug Control Agency (DCA) but by the research community as Malaysia become a more active participant in international drug research.

One significant step by the Ministry was establishing the steering committee for Clinical Research in 1997 with the main objective of the committee is to coordinate and encourage clinical trials in Malaysia.

Later, things began to change with the setting up of the National Institutes of Health (NIH) under the 7^{th} Malaysia Plan to address an urgent need to formulate strategies to strengthen health research in the MOH.

Around that time, the Clinical Research Centre was just an idea and it became operational in August 2000 as the clinical research arm of the Ministry and one of the seven institutes of the NIH focused on medical research.

In 2000 the name was changed to the "National Committee for Clinical Research, Ministry of Health Malaysia (NCCR)" as a ñsmart-partnershipsò of stakeholders with interests in quality clinical research.

Chaired personally by me, the committee task was to define research policies and priorities, develop research facilities and expertise, obtain funds, disseminate research findings and coordinate research activities of the Ministry.

PRESENT

Ladies and Gentlemen,

I am happy to report that since itôs establishment, the NCCR has provided oversight, developed clinical research guidelines, planned research infrastructure and human capital development and held forums for dialogue with Ministry, university and industry.

With the introduction of GCP training, and adoption of the International Conference on Harmonisation (ICH) / WHO Good Clinical Practice standards GCP, it is a requirement for clinicians conducting clinical trials to be GCP-certified.

The Medical Research & Ethics Committee (MREC) was established for scientific and ethical assessment to ensure that research conducted in the MOH met ethical standards to make certain patient safety is uppermost.

I would say that the ethics committee plays a crucial role in safeguarding the dignity, rights, safety of trial participants and to be extra vigilant in avoiding research which has been rejected as unethical in other countries.

If Malaysia is serious about becoming a clinical trials hub, than medical research ethics must given due attention by all stakeholders involved. I am happy to note that a training courses on ethics of clinical research was held here two-days earlier with Dr Cristina Torres, regional coordinator of the Forum for Ethical Review Committee in Asia and the Western Pacific (FERCAP) as one of the speakers.

We need more such training for those involved in clinical research to raise our standards and to avoid pitfalls such recent oversight issues in the United States where officials did not know how many clinical trials were being conducted.

With 200 inspectors and an estimated 350,000 testing sites, the Food and Drug Administration (FDA) audited only one percent of sites between 2000 and 2005, prompting the comment ñrats and mice get greater protection as research subjects in the United States than do humans.ò

The report by the US Department of Health and Human Services recommended the FDA develop a comprehensive internal database of clinical trials and institutional review board (IRB) registry (equivalent to MREC in Malaysia) for more effective inspection.

This is to be separate from the existing clinical trial registry maintained by the U.S. National Institutes of Health (NIH) in collaboration with the FDA since 1997 at clinicaltrials.gov

Registration of clinical trials is indeed a major issue of concern of the World Health Organization (WHO) Registry Platform with a mission to ensure that a complete view of research is accessible to all those involved in health care decision making.

We are fortunate that our man in WHO, Dr Tikki Pang, Director for Research Policy and Cooperation is here to share his strong views that registration of all interventional trials is a scientific, ethical and moral responsibility.

Indeed, the importance of early registration and transparency in clinical trials cannot be overemphasized as a central register that includes all trials, including Phase 1 trials, will allow reviewers to later ask for an accounting.

The initiative by the International Committee of Medical Journal Editors (ICMJE) in 2005 to call for registration of trials as a pre-requisite to publication has spurred recognition on the importance of public accountability.

In this regard, the MOH has made a significant step in the right direction with the National Medical Research Register (NMRR) that enables online registration at www.nmrr.gov.my that is clearly in line with international practice.

On 5 September 2007, I signed the official circular on the New National Institutes of Health (NIH) Guidelines that all research involving personnel, facilities or funds from MOH research grants be registered, reviewed and approved by appropriate authorities.

While registration on the NMRR ensures transparency and increases public trust in the conduct of medical research, when fully implemented it will help to considerably reduce processing time, enable easy access, captures data on research and allows management to track progress.

The NMRR has been pilot tested by the CRC and is being rolled out to all 16 CRCs nationwide as well as to all the research institutes under the NIH and, I am informed that training of individual secretariats, users and reviewers are underway.

Although still in transition stage, it has become clear that the NMRR, especially when fully linked to the MREC, will put in place mechanisms that will put us up to speed with FDA and WHO registration requirements.

As a step in the right direction in the move for Malaysia to promote itself as a clinical trial hub, I am confident that the NMRR will grow into a useful tool for clinical trial oversight and an invaluable resource that is accessible to public, sponsors and regulators.

It is the Ministryôs hope that more clinical research centres in Malaysia, whether in the private hospitals or in the universities, to register their studies

in the NMRR as a means of streamlining all clinical research activity in the country.

The Government has invested heavily in research and development under RM9 with an allocation of RM90 million for MOH and additional grants allocated for universities as well as for biotechnology that calls for better coordination of all clinically related research activity in Malaysia.

In biotechnology, CRC works closely with National Institute of Natural Products, Vaccines and Biologicals (now known as Ninebio Sdn Bhd or 9bio), Malaysian Biotechnology Corporation, Inno Biologics Sdn Bhd, and other biotechnology, pharmaceuticals and medical devices companies

This conference, the NCCR 2007, is organized in view of the growing interest in Malaysia and I hope will become a platform for global pharmaceutical and medical devices companies to outsource research here.

It should be an ideal learning and networking opportunity for investigators, industry sponsors, regulatory agencies and IRB/IEC members, and various providers of services to the clinical research industry.

Malaysia must seize the enormous potential offered in various phases of drug development research and use this opportunity to explore ways to translate advances in biomedical & clinical sciences into health benefits.

By attracting more clinical trials here, Malaysia will be able to offer opportunities for patients to enroll in trials of cutting edge treatments, and evaluate the effectiveness of disease-prevention strategies and processes.

To attract more clinical trials to Malaysia, the CRC has established a One-Stop-Centreò to meet the clinical research needs of industry by streamlining project management services that encompasses all clinical trial requirements.

Malaysia is fast becoming as leading country for clinical trial in Asia; and in moving up the value chain, the CRC is venturing into niche areas like Phase 1 or ñFirst-in-Manò clinical trials in specialised therapeutic areas.

I recently laid the foundation stone of what will be the first dedicated clinical trials facility with potential for early phase testing of new disease treatments in the Clinical Research Centre of Sarawak General Hospital.

With facilities such as this, I foresee that Research & Development in Malaysia will be more targeted and specific in line with new discoveries in biotechnology and its applications in traditional and complementary medicine (T/CM).

FUTURE

Ladies and Gentlemen,

The nation has just celebrated 50 years of independence and is already charting the direction for another 50 years of sustained achievement. Could we venture a guess on where clinical research will be in Malaysia in the year 2057?

By 2057, Malaysiaôs wealth in biodiversity should yield medicinal and therapeutic benefits that would place the nation at the forefront of the entire drug development cycle, from ñseed to pillò as it were.

The aims of the National Biotechnology Policy would have been achieved with the transformation of Malaysia as a global player in the application of living organisms, their components, biological systems and processes into healthcare benefits.

Most certainly, we need to target specific active ingredients with medicinal properties found in our native flora and fauna, identify its mode of action, develop methods of extraction that meet global standards and properly conducted clinical trials for undisputed proof of benefits.

I expect that offshoots from R&D in biotechnology will seed the medical devices, pharmaceutical and healthcare industry with homegrown products and services and move Malaysia beyond being an outsourcing option into becoming a necessary partner in the value chain.

If Malaysia intends to enter the big leagues as a drug developer, we will need to push the clinical research sector to a higher level with state of the art facilities, cutting edge equipment and world-class human capital. Can we do it?

Fifty years ago we did not even dare to think that we would be sending a man into space but now we have done it. Dare we dream that Malaysia could

one day be a major drug discover and vaccine developer for the global market. Why not?

Already Malaysia is taking the lead with the recent report that the world's first halal vaccine for meningitis to be produced by Universiti Sains Malaysia (USM) within two years. Also, RM1.9 billion has also been allocated to 9bio to restart vaccine production for the halal market.

Such developments follows closely those of Asian nations such as Japan, India, China, South Korea and Singapore are gearing up to join in the discovery of drugs for the worldwide markets by working with pharmaceutical multinationals.

The latest news is the Government of South Korea is aiming to develop at least one new drug to be marketed by Korean companies every year from 2016 that would generate an estimated annual sale of USD$1 billion.

I am sure that with continued government commitment to fund research programmes, build infrastructure and human capacity for R&D, biotechnology will be the main driver for Malaysia aspirations to be a drug discoverer and developer.

Already, industry analysts are predicting that nanomedicine could completely displace certain classes of drugs such as current chemotherapy agents with novel nanoparticle reformulations.

Pharmaceutical companies are zooming in on nanomedicine as an emerging area with recent advances in nanotechnology-related drug delivery platforms such as dendrimers, nanoshells, nanoparticles and nanoliposomes.

There is also the challenge of personalized medicine where a patient's genotype and clinical data would enable doctors to treat with accuracy, efficacy, safety and speed at the time of administration. Are we ready to tackle these advances?

I may not be able to answer those questions but I do know that no matter what, ultimately all new disoveries in pharmacuetical, medical device or treatment regimes will need to undergo clinical trial. In that sense, Malaysia is well placed.

I take this opportunity to thank all who worked hard to make this conference a reality including the Clinical Research Centre, Malaysian Biotechnology Corporation, EMP Asia, Quintiles Asia Pacific, Novartis and other industry participants.

With that I wish you a good conference. For our foreign visitors I wish you a pleasant stay and I hope you have discovered that Malaysia is indeed truly Asia. Have a safe journey home and we look forward to seeing you again in future.

Thank you.