

# National Committee for Clinical Research

**BULLETIN**

• 1 •

**2011**

## SECTIONS:

ACADEMIC CLINICAL RESEARCH  
BIOEQUIVALENCE STUDIES  
COMPLEMENTARY MEDICINE  
GLOBAL INITIATIVES & INDUSTRY UPDATES  
GOOD CLINICAL PRACTICE  
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**The NCCR bulletin** aims to disseminate information on latest clinical research policies and guidelines as well as to feature articles on Malaysia's progress and pioneering attempts in this industry. The content is prepared and compiled by the members of the National Committee for Clinical Research (NCCR) who consist of Ministry of Health personnel, academicians and industry professionals actively involved in clinical research activities in Malaysia. The compilation of articles in each issue reflects the diverse range of clinical research areas and thus offers readers the opportunity to appreciate various perspectives on issues related to clinical research in Malaysia.

**IN THIS ISSUE** we feature Malaysia's move of implementing bioequivalence study requirements for generic medicines, the launch and promotion of Clinical Research Malaysia to promote clinical research and the highlights from this year's National Conference for Clinical Research. We also discussed the lack of conclusive evidence for the therapeutic use of energy medicine and the potential of Malay postnatal care in hospitals. Finally, we included a review on Epstein Barr virus (EBV) and non-EBV related lab-based diagnosis tests for nasopharyngeal carcinoma.

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# FOREWORD

by Director-General of Health, Malaysia

As this is my first message for the NCCR bulletin, I would like us to get back to basics. This is a call to all those who have always wanted to do research but have not come around to do it. As the National Committee for Clinical Research, our task is to proactively create a favourable environment for clinical research in Malaysia; our tenacity is not only to encourage the industry but also the researchers. This goal is directly in line with the nation's aspiration for Malaysia to become a strong research force in the region.

I strongly believe that only those who are interested in research should be researchers as nothing worthwhile can ever materialise without passion. On that note, I also want to stress that research activity does not dictate clinical excellence. We have many excellent doctors, nurses, pharmacists and others in our field whose focus is patient care. This is what we need and this is what we should always prioritise. So I am not in a quest to transform all healthcare professionals into researchers. Instead, I am in a quest to transform the sombre attitude of those who want to do research but are reluctant to take the initiative. If you had any doubts before, the time has come to shed the cloth of reservation and to embrace a can-do attitude.



Although our aim in clinical research is to quench our scientific curiosity, the underlining goal should always be because we want to advance the health and quality of life of our patients. As we have been entrusted to protect their safety

against unscrupulous research practices, we have to be careful and vigilant at all times ensuring that research ethics is able to cater to the growth of medical science and technology. This is not just for the ethics committees to ponder on, but is also the responsibility of every respectable researcher. Sometimes, we have to reevaluate our motives and decide not on whether if we can do a particular research, but whether if we should. As ethical issues are not new and not confined to only some countries, we should adopt good international practices and avoid the practices that infringe on our nation's cultures. As important as it is for Malaysia to be recognised internationally for its attributes, it is equally important to conduct research that is relevant and important to its people. You will find these diverse set of topics being discussed in this issue of the bulletin.

Thank you

**DATO' DR HASAN ABDUL RAHMAN**

# The Implementation of Bioequivalence Studies on Generic Medicines in Malaysia

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## Requirements for registration

The Ministry of Health, Malaysia has enforced the registration of medicines through its regulatory body, the Drug Control Authority (DCA). As stipulated under the Control of Drugs and Cosmetics Regulations 1984, all medicines must be registered with the DCA before they can be manufactured, imported, distributed or used in Malaysia. In line with international standards, all medicines regardless of whether they are innovators or generic medicines undergo a scientific evaluation process to establish their safety, quality and efficacy before they are marketed in Malaysia.

## Bioequivalence (BE) study requirements on generic medicines

Generic medicines contain the same active ingredient and are indicated for the same use as the innovator medicines and therefore must be the same in all respects to ensure that they can be used interchangeably. As generic medicines contain well documented active ingredients, it is the global practice to accept bioequivalence studies in lieu of clinical trials as proof of quality, safety and efficacy.

The Ministry of Health has made the conduct of bioequivalence studies on generic medicines a mandatory requirement since 1999 and to date, there are 141 active ingredients for which bioequivalence studies are required as a prerequisite for registration.

Bioequivalence studies should be performed in clinical research centres. Since the implementation of BE requirements in Malaysia in 1999, there are now six (6) BE research centres in Malaysia, mostly located in universities.

Bioequivalence studies are conducted using **humans** as subjects; the plasma concentration versus time curve is used to assess the rate ( $C_{max}$ ) and extent of absorption (AUC). To show bioequivalence, a 90% confidence interval limit in the range of 80-125% based upon a logarithm transformed AUC and  $C_{max}$  data is needed; and this has been adopted by most of the drug regulatory bodies in the world.

Two medicinal products containing the same active substances are considered bioequivalent if their bioavailabilities (rate and extent) after administration in the same molar dose lie within these acceptable predefined limits. These limits are set to ensure comparable

*in vivo* performance, i.e. similarity in terms of safety and efficacy. Bioequivalence studies **do not** prove that two medicines of the same drug are **exactly identical**, but it shows two medicines **are similar enough** to be regarded as equivalent within specified limit that are clinically tolerable.

In view of the importance of bioequivalence studies to the effectiveness of generic medicines, the DCA has always taken a serious view on matters related to this requirement. Since its implementation, a total of **229** registered medicines have been cancelled and suspended due to failure to comply with this requirement. Since 2008, DCA has rejected a total of **135** new applications for registration because the applicants failed to submit adequate and satisfactory bioequivalence study data.

After a medicine has been registered with the DCA, it is possible that the manufacturer may make some changes on the source of active ingredients used, manufacturing process involved, etc. As all these changes may have implications on the quality, safety and efficacy of the registered product, it is mandatory for companies to seek prior approval from the DCA before making any changes to these registered products. Data must be provided to substantiate that the quality, safety and efficacy is not compromised through these changes. Punitive actions can be taken against any companies that do not conform to these requirements.

## Action Plan

Although at the moment, requirements for BE studies are only enforced for products containing the selected 141 active ingredients, the DCA recently has issued a new directive for the implementation of the following:

- i. Bioequivalence studies is required for all generic medicines which are in the form of immediate release, oral solid dosage starting from 1st January 2012.
- ii. Accreditation of local BE centres with regards to the Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) in 2012.
- iii. Inspection of overseas BE centres for compliance to GCP and GLP in 2012.

The implementation of BE studies as part of the requirement for registration provides an added value for the government, pharmaceutical industries, healthcare sectors and also the consumers/patients. The implementation of BE studies would help to reduce the costs of medicines by reducing the import of innovator drug products, as well as reducing the healthcare costs by increasing the use of generic medicines which are admittedly much cheaper.

The requirement for BE studies for all generic medicines should boost local pharmaceutical industries to produce higher quality products which can enhance export opportunities for local products to the global market and increase

the country's revenue, leading to economic growth and progress.

The need for BE studies will encourage national BE centres to intensify their abilities to comply with international standards. It is important to upgrade existing facilities to achieve the targeted standards needed to conduct BE studies. Establishing more BE research centres that comply with international standards will make the industry more competitive.

### **Conclusions**

Malaysia should be able to show a high level of performance in components that are considered important in the pharmaceutical industry as Malaysia is among the most rapidly developing countries in the region and is the earliest country to enforce BE study requirements for generic medicines. Malaysia should not be defeated by other countries in the region which are clearly still at the earlier stages of enforcing BE study requirements. Bioequivalence study centres should enhance and improve standards so that they can become the centres of research that would invoke interests of manufacturers, both local and abroad manufacturers to conduct BE studies in Malaysia. Bioequivalence study centres with world-class infrastructure, facilities and skilled personnel which comply with international standards will ultimately lead to global recognition, thus enabling Malaysia to be a centre for BE excellence.

# Evidence Based Energy Medicine

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Energy medicine is one of five domains of Complementary and Alternative Medicine (CAM) as classified by the National Center for Complementary and Alternative Medicine (NCCAM), National Institutes of Health, United States of America. Energy medicine uses energy fields as treatment and there are 2 groups according to the treatment approach; BIOFIELD THERAPIES such as Reiki, Qi Gong, Aura Metaphysics, Phytobiophysics and Bach Flower Remedies and BIOELECTROMAGNETIC BASED THERAPIES such as Crystal Healing and Colour Vibration Therapy [1].

Presently there are eight practices classified under energy medicine namely Qi Gong, Reiki, Bach Flower, Colour Vibration Therapy, Aurametaphysics, Raoha, Phytobiophysics and Crystal Healing. Although energy medicine is gaining popularity, these approaches are still controversial due to the lack of convincing findings to confirm their benefits [2].

The Traditional and Complementary Medicine Division of Malaysia's Ministry of Health reviewed latest research articles on energy medicine to assess the effectiveness of energy medicine in treatment of medical conditions (either as therapy or for wellness). Pubmed was the database used for the search of articles. English articles published within the last 5 years

were included. Only articles on Qi Gong, Reiki and Bach Flower were relevant.

- **Qi Gong**

Systematic reviews suggests that Qi Gong may have positive effects in lowering blood pressure and treating type 2 diabetes, and may result in psychophysiological outcomes. However, as most of the trials are of low quality, had high risk of bias and had very limited reliability, we cannot conclude that Qi Gong is an effective therapy for these medical conditions [3,4,5].

Likewise, a systematic review evaluating external Qi Gong for pain conditions also found encouraging but unconvincing findings. The studies had small sample sizes [6]. The evidence to suggest that internal Qi Gong is beneficial for treating pain and as therapy for cancer is far from convincing [7,8].

- **Reiki**

All five systematic reviews stated that the evidence is insufficient to suggest that Reiki is an effective treatment for any condition owing to the paucity of well designed trials. Most of the studies are weak due to sampling, methodological and statistical flaws with high risk of bias [9-13].

- **Bach Flower**

A systematic review suggested that the evidence regarding Bach Flower Remedies for psychological problems is very limited and the majority of the studies have methodological problems. The authors concluded that the current available evidence indicates that Bach Flower Remedies are no more efficacious than a placebo intervention for psychological problems, but is probably as safe [14].

Evidently, future research is needed to establish a rigorous evidence for energy medicines. Until more evidence is available, the most promising indication for energy medicine seems to be related to its wellness properties.

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## Malay Postnatal Care in Hospitals

*Aidatul Azura Abdul Rani*

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As our locals have practiced Traditional and Complementary Medicine (T&CM) since the 15th century, the National policy of Traditional and Complementary Medicine Division, Ministry of Health aims to integrate T&CM into the Malaysian healthcare system.

The Malaysian government has implemented various programmes to address maternal and child health and to reduce maternal and childhood mortality. One such move was the introduction of postnatal massage service in Putrajaya Hospital on 17th July 2009. This service was later also offered in Sultan Ismail Hospital, Johor Bharu. The establishment of postnatal service at the T&CM unit is to promote safe practices in the Malay postnatal care and provide information to discourage any potentially harmful beliefs that may affect the morbidity and mortality of new mothers.

The prevalence of postnatal depression in women ranged from 5 – 25%. The incidence of postnatal depression is low in Malaysia at 3.9% due to the vast majority of Malaysian women still observing the traditional postnatal beliefs and practices [1]. Traditional Malay postnatal care is said to prevent “meroyan” (postnatal psychosis) as this complication may arise during the postnatal period.

Malays postnatal period is called ‘masa dalam pantang’ which means ‘confinement period’. During this time, the woman’s behavior in relation to diet, activity and hygiene is determined by tradition, which underlies some beliefs and practices. The confinement period lasts for 40 to 44 days (6 weeks). There are three major features in Malay postnatal care, which are the use of herbs, heat and the Malay postnatal massage. In the integrated hospital settings, the services offered are for wellness postnatal massage and midwifery care. The wellness postnatal massage consists of Malay postnatal wellness massage and breast care. The aims are to relief muscle cramps or fatigue after labour, to give awareness and promote safe practices of traditional postnatal care as well as to promote compliance in breastfeeding programme. As for the midwifery care, it consists of whole body massage, hot compression and body wrapping/binding. This stage in care is to detect postpartum complications early, promote a safe and good practice of Malay postnatal care and create awareness of the safe use of herbal concoction during confinement period [2].

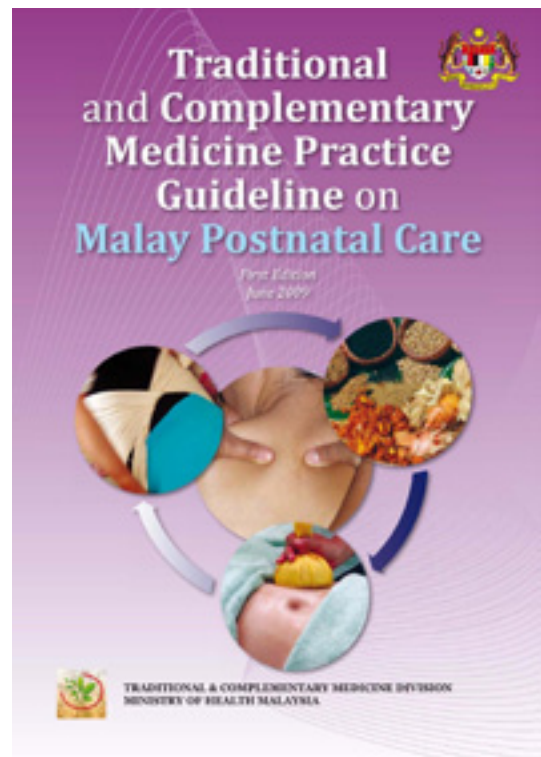
The traditional Malay postnatal care offers wonderful claims and benefits which have yet to be proven. The improvement of physical and mental status of women receiving this treatment



is yet to be assessed and thoroughly researched. Research to recognise the associated risks, and the safety and effectiveness of the practice has to be carried out. We wish to preserve this rich heritage by developing a well-established standard of practice and promote its benefits through formal training, education and research.

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## 5<sup>th</sup> National Conference for Clinical Research Focus on Transforming Clinical Research in Malaysia

There was an electric sense of urgency at the 5th National Conference for Clinical Research when, on 22 June, Health Minister Dato' Sri Liow Tiong Lai turned up early to jumpstart the transformation process.

Despite a punishing work schedule and Parliament, the Health Minister made a point of keeping his appointment with NCCR 2011, to launch both the conference and Clinical Research Malaysia (CRM). The CRM is an Entry Point Project 2 (EPP2) under the Healthcare National Key Economic Area (NKEA) of the Economic Transformation Programme (ETP), both as an economic growth engine and to improve the well being of the rakyat.

Clinical Research Malaysia will function as a non-profit, governmental, site management organisation to attract clinical trials to Malaysia by facilitating access to the country's extensive network of clinical research centres. The CRM provides access to the Ministry's network of 341 hospitals and hundreds of clinical trial sites, and professional linkages with CRCs established in private hospitals and medical universities nationwide.

In his speech, YB Dato' Sri Liow said: "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."

He added that compelling reasons for the transformation include 23 tertiary hospitals linked within the Network of Clinical Research Centres with nine identified as Centres of Research Excellence (CoRE) by therapeutic areas. These CoRE hospitals are: Sarawak General Hospital in Kuching, Sarawak; Queen Elizabeth Hospital in Kota Kinabalu, Sabah; Hospital Raja Permaisuri Bainun 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.

YB Dato' Sri Liow added: "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



**MEET AND GREET:** Health Minister YB Dato' Sri Liow Tiong Lai took time to chat with NCCR 2011 conference speaker Prof. Sim Kui Hian (left), visiting senior cardiologist, Sarawak General Hospital.

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.”

In Asia, Malaysia stands apart with well-established data resources such as patient registries in major therapeutic areas that enable fast recruitment of clinical trial subjects that makes the clinical research ecosystem attractive.

In addition, the mandatory registration in the National Medical Research Register (NMRR) for research conducted in government hospitals also gathers useful information for monitoring adverse events and tracking the number of medical publications.

As of May 30, 2011 the total number of Industry Sponsored Research (ISR) is 237, i.e. 164 ongoing clinical trials as of 1 Jan 2011 and 73 new trials from 1 Jan to 31 May 2011. The target set by ETP is 1,000 clinical trials by 2020. To achieve



**SIGNED AND SEALED:** Dr Goh Pik Pin (left) and Apurya Shah in a symbolic handshake after signing the memorandum of agreement, witnessed by YB Dato' Sri Liow Tiong Lai (centre), Dato' Dr Hasan Abdul Rahman (extreme left) and Dr Maurice Cross (hidden).

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.

Following the launch, YB Dato' Sri Liow witnessed the signing of a memorandum of agreement between Veeda Clinical Research (SEA) Sdn Bhd, and the MOH for the setting up of Veeda's advanced research unit at the Ampang Hospital in Kuala Lumpur.



**THAT'S INTERESTING:** Director-General of Health Dato' Dr Hasan Abdul Rahman stops at a booth to see what's on display.

The Ministry was represented by Dr Goh Pik Pin, Director, Clinical Research Centre while Veeda was represented by Group Managing Director Apurva Shah. Also present were Director-General of Health Dato' Dr Hasan Abdul Rahman and Dr Maurice Cross, Veeda Group Medical Director. Keeping to a brisk pace, YB Dato' Sri Liow never let up as he whisked through the exhibition booths and stopped to field questions from journalists during the press conference before rushing off to Parliament.

## Conference Highlights

The National Clinical Research Agenda took centre stage at the 5th National Conference for Clinical Research (NCCR 2011) as speakers and participants shared stimulating discussions on clinical trials, databases and registries.

Sharing the Australian experience were Professor Helena Britt, Director, Family Medicine Research Centre, University of Sydney and Ms Jenny Hargreaves, Group Head, Economics and Health Services Group, Australian Institute of Health and Welfare (AIHW). Ms Hargreaves shared that the Australian Hospital Statistics produced multiple outputs based on the same underlying data that include government reports, student educational materials, media, private sector, health sector interest groups, health policymakers and national agencies.

Prof. Britt shared insights on the BEACH (Bettering the Evaluation And Care of Health) Program which is designed and conducted by the Family Medicine Research Centre of the University of Sydney and is now in its 14th year. The BEACH database, with 1.3 million GP-patient encounters, is reported in two books annually and had been published in almost 200 journal articles. It is used extensively to inform policy planners and to measure the impact of policy changes.

The United Kingdom-based Dr Maurice Cross, Group Medical Director of Veeda Clinical Research shed light on the perfect storm in the pharmaceutical industry, with job losses and global financial uncertainties. Alluding to a “New World Order” in the Contract Research Organisation market, Dr Cross urged Malaysia

to aim for early development for new clinical entities (NCE) from Japan, and to be haven for Indian pharmas seeking alternative sites.

Similarly, Singapore’s Dr Melvyn Teillol-Foo, Chief Medical Officer and Managing Director, RegAff Pte Ltd and SingEval Pte Ltd., urged Malaysia to grasp the opportunity to develop a ‘green-field’ environment for early clinical development. By learning from mistakes and burdens of ‘industry history’ from established nations, Malaysia can embark on a fresh start with a coherent master plan, with speed to product registration far outweighing the early development costs.

Dr Hasenah Ali, Senior Principal Assistant Director, Centre for Investigational New Product, National Pharmaceutical Control Bureau (NPCB), elaborated on GCP and GLP compliance requirement for BE studies effective from January 2012. Certification will involve inspection from NPCB to verify specific elements in the facility, handling procedures, validation of the bio-analytical methods, equipments, documentation, pharmacokinetics and statistical analyses.

Universiti Malaya Law Professor, Dr Abu Bakar Munir, highlighted aspects of the Personal Data Protection Act (PDPA) 2010 that impact patient registry and health care databases, as data cannot be used for other purposes nor can the data subject be identified. Citing that privacy should not be a barrier to research as it is an essential part of the social relationship, Abu Bakar believes the PDPA is a useful tool for researchers as it helps build trust in research activities.

## DIA Chicago 2011 Spurs Future ASEAN Collaboration in Clinical Trials

Clinical Research Malaysia's (CRM) recent participation in the 47th annual meeting of the Drug Information Association or DIA Chicago 2011, from 19 – 23 June 2011 has Datuk Dr Teoh Siang Chin abuzz with energy. The DIA is a neutral, nonprofit, global, professional association of nearly 18,000 members who work in every facet of the discovery, development, and life cycle management of pharmaceuticals, medical devices, and related products

Recently returned from Tawau, Sabah, Dr Teoh now heads CRM, the newly launched Entry Point Project 2 (EPP2) created under the Healthcare Economic Transformation Programme (ETP).

The CRM's vision is to establish Malaysia as a preferred destination for clinical contract research with its multiracial profile and an ecosystem conducive for drug research and clinical trials. Launched by the Minister of Health, YB Dato' Sri Liow Tiong Lai at the 5th National Conference for Clinical Research on 23rd June 2011, CRM targets to draw 1,000 clinical trials by 2020.

By being at DIA Chicago 2011, CRM had made Malaysia known, said Dr Teoh, "The DIA is the global platform for drug research and we wanted to make an impact, to inform that Malaysia is in the market."

"We have to catch up as we are about 47 years behind. We did test the waters in DIA San Diego

2009, as the Clinical Research Centre's One-Stop-Centre but we didn't have a firm platform for contract research."

"As CRM, we have paved the way for our continued presence at DIA. This is important if Malaysia is to be the entry point for pharmaceutical companies and contract research organisations (CROs) into this region."

Among the trends he noted at DIA Chicago was the extensive use of mobile devices and smart phones and iPads to scan QR codes on business cards, posters, and just about anything.

Impressed with the well-organised event, Dr Teoh said, "CRM will need to follow new trends like data-in-the-cloud that allowed the organisers to keep participants informed. It was a lesson in hospitality."

He said, "We enticed people to our booth decorated with orangutan stuffed toys and souvenirs from Sabah Tourism Board, which we also gave away. It brought the highest traffic in our area."

The CRM team met with CEOs of CROs and Pharmas who were invited through their Malaysian office and one surprise visitor, DIA President Dr Richard O. Day, accepted their invitation to drop by the booth.

Dr Teoh said, “With Dr Day, we discussed holding a regional meeting, the first DIA ASEAN in 2013, in Malaysia which we intend to pursue. We also met with Dr Jane Y. Cai, Director DIA China, who is based in Beijing. This is one of the success stories of DIA.”

On CRM, Dr Teoh said, “For now, we remain a not-for-profit government entity as this gives us easier access to public healthcare facilities. By next year, we hope to have infrastructure and operational processes in place.”

“CRM is also keen to collaborate with our ASEAN neighbours as we don’t see them as competitors. If we want to attract more global multicentre trials into this region, we need to work together.”

“That is why we want to do DIA ASEAN in Malaysia. We can’t push forward our agenda for clinical research without working with them. Instead of talking to each country separately, let’s talk at the ASEAN level.”

Take for instance, the generic drugs that Malaysia is targeting under EPP3. These drugs will need to undergo Bioavailability (BA)/ Bioequivalence (BE) testing to ensure quality, efficacy and safety before they can be registered.

Much of the BA/BE clinical trials for generic

drugs are outsourced to countries such as India and China, and with Malaysia as the lead country for BA/BE studies in ASEAN, there is a need to grow the sector.

Dr Teoh foresees a need to work with partners such as private hospitals to expand their research component by helping them to set up facilities capable of undertaking BA/BE clinical trials.

This will be a huge industry as many major drugs go off patent in 2012, and less costly generics with the same active ingredients will become readily available. Under EPP3, Malaysia intends to increase generic drugs manufacturing for export.



**LOOKING TO HOLD DIA ASEAN IN 2013** – (Left to right) Datuk Dr Teoh Siang Chin, Head CRM, discussing the possibility of holding DIA ASEAN with Dr Richard O. Day, President, Drug Information Association (DIA), Dr Ong Loke Meng, Technical Advisor CRM and Dr Thevendran Sadasivam, Deputy Head CRM at the DIA Chicago.

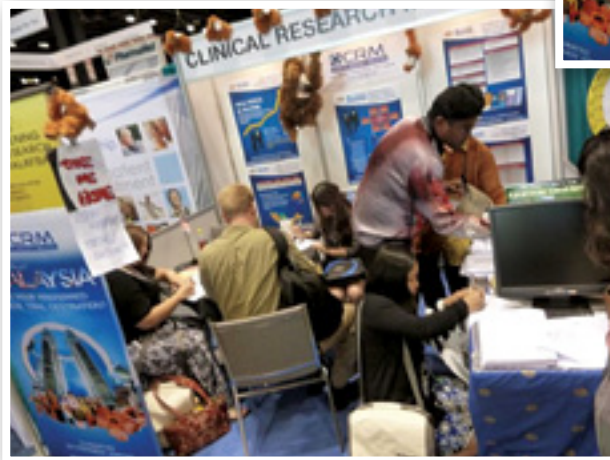
In some ways, DIA Chicago was literally an opportunity to put Malaysia on the map as some had no clue where it was. The CRM’s four-member team was kept busy explaining the clinical trial scenario in Malaysia.

Aside from explaining that the cute little monkeys were called Orang Utans, the team also explained the services CRM could provide should they choose to run clinical trials in Malaysia.

Malaysia is actively developing capability in all phases of clinical trials and beefing up peripheral industries like record management,

supply chain, laboratory services, security agent, insurance industry, etc.

Far from feeling small, the team felt that Malaysia had all the essential elements that needed to be consolidated into a more efficient ecosystem to attract clinical trial outsourcing our way.



**ENTICED BY THE ORANGUTANS**  
– The Clinical Research Malaysia's booth lured a steady traffic of visitors who were curious about the orangutans decorating the booth and about doing clinical trials in Malaysia.

## Generic Drugs Is Now A Matter of Policy

The recent report that the Ministry of Health has implemented a generic drugs policy as replacement for original medicines or patented drugs at government hospitals nationwide comes as no surprise.

This policy is very much in line with the Entry Point Project 3 (EPP3) of the healthcare National Key Economic Areas (NKEA) that aims to make Malaysia a major exporter of generic drugs.

The policy calls for hospitals under the Health Ministry to replace ten original medicines with their generic equivalent manufactured locally when the intellectual property rights of the drugs expire.

In view that Malaysia provides medical subsidies at government hospitals and clinics nationwide, the use of generic drugs that has already been implemented in many countries, will mean access to cheaper medicines.

The patent expiration of major blockbuster drugs over the next 10 years will provide opportunities for Malaysia to export locally manufactured generics estimated to be worth RM435 billion.

As the only Organisation of The Islamic Conference (OIC) member country in the PIC/S (Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme), Malaysia has the halal advantage.

Construction of manufacturing facilities with dedicated production lines in specific therapeutic

areas will boost Malaysia's capability of large-volume production of generic drugs with recent patent expiries.

As driver, the MOH will implement and enforce policies such as the National Medicines Policy that requires the local production of specified patented drugs that are sold to the public sector.

Another regulatory change MOH will look into is the requirement for bio-equivalence testing in the registration of all generics products with the Drug Control Authority for categories of immediate release oral solid dosage products (see page 3 for article)

Publication of the 'Malaysian Guidelines for the Conduct of Bioavailability and Bioequivalence Studies' will provide guidance in conducting BE Studies in accordance to established international standards.

Member Countries of the Association of Southeast Asian Nations (ASEAN) will look into the acceptance of the BE Studies conducted by recognised BE Centres in the region in order to reduce unnecessary repetition.

The ACCSQ (ASEAN Consultative Committee for Standards and Quality) – PPWG (Pharmaceutical Products Working Group) is chaired by Malaysia and helmed by Dato' Eisah Abdul Rahman, Senior Director of Pharmaceutical Services Ministry of Health.



# Review: Lab-based Tests for Nasopharyngeal Carcinoma

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## Introduction

Nasopharyngeal carcinoma (NPC) is a malignancy originating from the epithelial cells lining the nasopharynx. The incidence rate of NPC is especially high in Southern China and parts of Southeast Asia [1]. The Bidayuh of Sarawak are among the high-risk populations [2]. Within Peninsular Malaysia, NPC is one of the ten most common cancers as well as the most common cancer among 15-49 year-old men [3, 4].

In Malaysia, most of the NPC patients are usually diagnosed at the late stages due to the vague symptoms of the disease [5]. Late diagnosis was shown to be the cause of low survival rate [5-8], hence it is essential to establish a screening method for the early diagnosis of NPC and prognosis of treatment outcome for a better survival rate.

Current methods of diagnosis in the clinical settings include but are not limited to: 1) histological examination of biopsy samples, and 2) non-invasive imaging methods such magnetic resonance imaging (MRI), computed tomography (CT) and positron emission tomography (PET). The invasive nature of biopsy collection and high cost of radiology imaging are the major drawbacks which refrain

health policy makers to set these tests for NPC screening. Up to date, many lab-based diagnosis tests were developed in the hope to achieve cost effectiveness, and high sensitivity and specificity. Almost all of the extensively studied and evaluated non invasive tests for NPC are Epstein-Barr virus (EBV) centered and the relatively few non EBV tests for NPC are still at their preliminary state. Based on the high association of EBV with NPC, the EBV centered strategy has its advantages but inevitably has missed out a minor NPC patients subtype – the World Health Organization (WHO) type 1 NPC which is usually negative for EBV [9].

## EBV related lab-based tests for NPC

As EBV is known to be an aetiological factor that plays an important role in the pathogenesis of NPC, majority of currently available tests for NPC are EBV centered: the tests either detect EBV antigens, related antibodies and/or EBV DNA in circulation of NPC patients. Some of the EBV related tests include serology which detects host IgA/IgG against EBV antigens (i.e. viral capsid antigen (VCA), early antigen (EA), and EBV nuclear antigens (EBNA)), anti-EBV DNase antibody and EBV DNA viral load (Table 1) [10-18].

Table 1. Epstein-Barr virus lab-based diagnosis test of nasopharyngeal carcinoma

References	Studies	Sensitivity (%)	Specificity (%)
Mutirangura <i>et al.</i> 1998 [10]	EBV DNA	30.1*	100*
Lo <i>et al.</i> 1999 [11]	EBV DNA	96.5	93.0
Shotelersuk <i>et al.</i> 2000 [12]	EBV DNA	58.7	87.0*
Hsiao <i>et al.</i> 2002 [13]	EBV DNA	58.7*	89.3*
Leung <i>et al.</i> 2004 [14]	EBV DNA	95.0	98.0
	EBV VCA-IgA	81.0	96.0
	Combination	99.0	NA
Stevens <i>et al.</i> 2006 [15]	EBV DNA,	90.0	98.0
	BARF1 mRNA	74.4*	100*
Fachiroh <i>et al.</i> 2006 [16]	EBNA1-IgA	88.6	80.1
	VCA-IgA	79.8	70.9
	Combination	85.4	90.1
Gu <i>et al.</i> 2008 [17]	VCA-IgA	91.9	83.8
	EBNA1-IgA	80.0	80.0
	Diffused EA-IgA	92.6	90.8
	Diffused EA-IgG	85.2	82.3
Luo <i>et al.</i> 2009 [18]	VCA-IgA	90.0	89.5
	EA-IgA	75.0	94.7
	Anti-EBV-DNase	76.3	90.8
	EBV DNA	68.8	88.2
	Combination	98.8	84.2
Ayadi <i>et al.</i> 2009 [19]	EBNA1-IgA	90.7	92.0

Key: \* calculated based on published results NA, data not available.

Detection of EBV DNA in NPC biopsy samples has sparked the interest of whether EBV DNA could be detected in the circulation and the possibility of it as a diagnosis marker. Several studies reported the detection of EBV DNA in the blood of NPC patients [10-14, 20, 21] and a correlation between EBV DNA viral load

and disease stage [20, 21]. EBV DNA viral load was also shown to have correlation with the apoptosis of tumour tissues [10], indicating that EBV DNA could be released into the circulation as a result of cell death. The EBV DNA viral load can accurately reflect treatment response [22]. Albeit remarkable predictive value of EBV DNA

for treatment response, the potential use and feasibility of EBV DNA viral load as a screening tool for the general public remain unclear. The sensitivities for circulating EBV DNA in various studies deviate from 30% to 96.5% (Table 1). Stevens et al. [23] suggested that this could be due to the instability and degradation of EBV DNA in the plasma/serum. To overcome this issue, a testing of EBV DNA load from nasal brushings (NP) was recently developed [15]. As the follow up study for this test is still on-going, the sensitivity and specificity of this test for the screening of general populations is yet to be elucidated.

Aside from EBV DNA viral load, extensive studies have reported increased serum EBV VCA-IgA levels in NPC patients [24, 25], indicating that VCA-IgA could be a good biomarker for screening NPC. In 3 recent NPC screening and follow up studies involving at least 9,000 subjects from the general population, although the relative risk of NPC in seropositive subjects is at least four fold higher than in the seronegative subjects, more than 50% of NPC cases detected during the follow-up period were actually from the seronegative group [26-28]. This gave a hint of ambiguity in the value of serology tests for screening NPC in the general population. The feasibility as well as cost effectiveness of employing these serological tests for NPC screening thus remains controversial.

### **Non EBV related lab-based tests for NPC**

Apart from the EBV-related markers, molecular diagnostic biomarkers investigated for NPC

detection include plasma RNA integrity, serum metabolites and DNA methylation test from nasal brushings.

In the circulation of NPC patients, increased RNase activities were observed [29]. Another recent study revealed that serum metabolites could be potential biomarkers for the diagnosis and therapy of NPC [30]. It was shown that serum levels of hydroxyphenylpyruvate, N - a c e t y l g l u c o s a m i n y l a m i n e , N-acetylglucosamine, and kynurenine were significantly increased in NPC patients compared to throat cancer patients and healthy controls. In addition, these 4 metabolites were shown to be increased concurrently with the stages of NPC and decreased after treatment with radiotherapy.

Meanwhile, a study conducted on nasal brushings showed that methylation analysis of several tumour suppressor genes can differentiate NPC subjects from the non-NPC ones. Combined analysis of p16, WIF1, CHFR and RIZ1 showed good discrimination between subject groups and was suggested as a risk assessment test alongside EBV-based markers [31].

The development of non EBV related lab-based tests for NPC is important as these tests do not exclude EBV negative NPC. Nonetheless, many of these tests are still at their preliminary stage and more efforts are needed to conduct and validate their specificities and sensitivities in large screening cohorts.

## Conclusion

Nasopharyngeal carcinoma is a very common cancer among Malaysians. Although the mortality rate of NPC is relatively lower compared to other cancers, in Malaysia, the mortality rate for NPC is still among the highest in the world [3]. Due to the lack of an effective screening test and early detection markers, these relatively curable cancer patients were not diagnosed and given the proper treatments until NPC had progressed to advanced stages. In order to reduce the disease burden, a good biomarker for screening and early detection of NPC is needed.

It may appear that many current lab-based tests had been developed and are almost ready for health-policy makers to adopt for screening and/or prognosis of NPC. However, recent studies [26, 27] revealed that these tests are not ready for general population screening – the false positive and negative results were higher than expected – and so the feasibility and cost effectiveness of these tests are not stratified. More research to look for better markers and perhaps combination of markers is needed. For example, it has been demonstrated that cell free microRNAs could be the next promising biomarker. Signatures of circulating microRNAs can be associated with diagnosis, disease stage and/or progression in different cancers [32-35]. In a latest study, both EBV and non EBV microRNAs are found to be deregulated in NPC patients [36, 37].

In conclusion, a screening test is needed to reduce the disease burden of NPC. Due to the

cost effectiveness and feasibility issues, lab-based tests for NPC are yet to be adopted into screening programs and large cohort of follow up studies have to be carried out in the general populations.

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## New Industry Sponsored Research Approved by Local Institutional Review Boards (IRBs) in 2011

IRBs	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Total
MREC	5	8	5	8	4	5	5	3	43
UMMC	2	3	1	4	1	3	5	3	22
HUKM	3	1	2	0	2	1	2	1	12
USM	0	0	2	0	1	0	0	0	3
JPEC	0	3	5	0	5	3	1	3	20
IJN	0	0	0	0	0	1	0	0	1
UPM	0	0	0	0	0	0	0	0	0
UITM	0	1	0	0	0	0	0	0	1
USM/Lam Wah Ee Hospital	0	5	0	0	0	0	0	5	10
UIA	0	0	0	0	0	0	0	0	0
IMU	0	1	0	0	0	0	0	0	1
SDMC	0	1	0	0	0	0	0	0	1
SMC	0	0	0	0	0	1	0	1	1
<b>Total</b>	<b>10</b>	<b>23</b>	<b>15</b>	<b>12</b>	<b>13</b>	<b>14</b>	<b>13</b>	<b>16</b>	<b>116</b>

Note: Data updated on 12 Sept 2011

### Ethics Committee

MREC: Ministry of Health Medical Research and Ethics Committee

UMMC: University Malaya Medical Centre  
HUKM: Hospital Universiti Kebangsaan Malaysia

USM: Universiti Sains Malaysia, Kubang Kerian

JPEC: Joint Penang Independent Ethics Committee

IJN: Institut Jantung Negara (National Heart Institute)

UPM: Universiti Putra Malaysia

UITM: Universiti Teknologi Mara

USM/Lam Wah Ee Hospital: Joint Ethics Committee of School of Pharmaceutical Sciences, USM and Hospital Lam Wah Ee on Clinical Studies

UIA: Universiti Islam Antarabangsa

IMU: International Medical University

SDMC: Sime Darby Medical Centre

SMC: Sunway Medical Centre.

## Number of Ongoing and New Clinical Research in Malaysia in 2011

	Number of Clinical Research	Cumulative Total
On-going research carried forward from year 2010	164	164
<b>2011</b>	<b>No. of new research</b>	
January	10	174
February	23	197
March	15	212
April	12	224
May	13	237
June	14	251
July	13	264
August	16	280
<b>TOTAL</b>	<b>116</b>	<b>280</b>
KPI set for Entry Point Project 2: Clinical Research Malaysia		260

**Good Clinical Practice (GCP) workshops*****Organiser***

Clinical Research Centre (CRC)

***Summary***

The CRC's nationwide tour is to ensure that every potential clinical researcher has the opportunity to learn from the experts and the experienced. Participants are taught on ICH GCP and Malaysian GCP, clinical research ethics, informed consent, clinical trial protocol and investigator's brochure, investigator's responsibilities and relationship with sponsor, adverse event monitoring and reporting, etc.

***Dates (City)***

1. 17–19 October 2011  
(Grand Seasons Hotel, Kuala Lumpur)
2. 15–17 November 2011  
(Grand Seasons Hotel, Kuala Lumpur)
3. 5–8 December 2011  
(Palm Garden Hotel, IOI Resort, Putrajaya)

**Email:** [contact@crc.gov.my](mailto:contact@crc.gov.my)

**Website:** [www.crc.gov.my](http://www.crc.gov.my)

**National Conference for Clinical Research (NCCR) 2012*****Organiser***

Clinical Research Centre (CRC)

***Summary***

The Ministry of Health (MOH) is tasked with achieving the aim of the Economic Transformation Programme to move Malaysia into the big leagues as a regional clinical trials destination. The MOH through the CRC, supports NCCR 2012 as a forum that brings together clinical investigators, industry professionals, regulatory agencies and policy makers to address issues and challenges to achieve this aim. By gathering people from various research disciplines, NCCR is hoped to foster constructive and forward looking discussions, sharing of experiences, and mutual commitment towards the betterment of humanity.

***Dates (City)******Main conference:***

26–28 September 2012 (Klang Valley)

***Pre conference workshops:***

23–25 September 2012 (Klang Valley)

Specific venue and programme will be confirmed soon

**Email:** [contact@crc.gov.my](mailto:contact@crc.gov.my)

**Website:** [www.crc.gov.my](http://www.crc.gov.my)

## About NCCR

Established in 1997 to coordinate and encourage clinical trials in Malaysia, the National Committee for Clinical Research (NCCR) supports the enhancement and regulation of the quality of biomedical research as well as clinical research practice in Malaysia. The NCCR is headed by Dato' Dr Hasan Abdul Rahman, Director-General of Health and it is managed by the Centre for Investigational New Product of the National Pharmaceutical Control Bureau, Ministry of Health Malaysia who acts as secretariat. The members of this committee consist of experts from Ministry of Health (MOH), various national universities, the Malaysian Pharmaceutical Society (MPS), the Pharmaceutical Association of Malaysia (PhAMA), the Malaysian Organisation of Pharmaceutical Industries (MOPI), and other non-governmental organisations. [www.nccr.gov.my](http://www.nccr.gov.my)

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