CRM bulletin
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Malaysia among the best in *cardiology* trials

Eminent cardiologists **Prof Dr. Sim Kui Hian** & **Tan Sri Dato' Seri Dr. Robaayah Zambahari** share their research journeys

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About CRM

Clinical Research Malaysia (CRM) is a non-profit organization wholly owned by the Government of Malaysia. It was established in June 2012 to promote Malaysia as a preferred global destination for industry sponsored clinical research (ISR). CRM provides a range of services to enable and facilitate sponsors (primarily from the pharmaceutical and medical device industries) and contract research organizations (CROs) to initiate a wide spectrum of clinical trials in Malaysia.

CRM's key functions encompasses three core components, the first of which is securing clinical trials. This is done through advertising and promotional activities, participation in key conferences, involvement in clinical trial distribution and strategic collaborations with major stakeholders. The second component involves closing the deals through a comprehensive feasibility study, convincing site review operation and implementation of an efficient financial, administration and approval process. The third component is conducting the trials. This is achieved through our high quality Study Coordinators and Principal Investigators, effective standard operating procedures, quality assurance of study sites and support services.

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MINISTRY OF HEALTH MALAYSIA

CRM CLINICAL RESEARCH MALAYSIA

Your Global Solutions in One Nation

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MINISTER OF HEALTH MALAYSIA

FOREWORD

"Moving on to 2014, the MOH remains committed to positioning Malaysia as a preferred destination for ISR..."

Clinical trials are a key tool for advancing medical knowledge and patient care. Since 2006, we have seen a steady and substantial increase in the number of industry sponsored research (ISR) being conducted both in private and government-owned hospitals and universities. The increase from 57 ISR trials in 2006 to an expected 224 trials in 2014 is a testament to the encouragement given by the government to promote ISR amongst the medical fraternity as one of the means of improving the healthcare system of the nation.

Malaysia has the potential to become the hub of ISR clinical trials among Asian countries due to our large pool of well-trained healthcare professionals, up-to-date medical technologies, multi-ethnic patient population and an excellent information and referral system within the Ministry of Health (MOH). Undeniably, Malaysia is an excellent place to conduct clinical trials and the promotion of clinical trials in Malaysia will enable us to tap into the global ISR industry, which is expected to be worth US$43 billion in 2017.

Towards this goal, I am pleased to note the publication of the 2nd issue of the CRM bulletin. This bulletin certainly has the potential to be an important tool to disseminate information, motivate more doctors to engage in ISR and attract industry interest to Malaysia. Thus, it is my sincere hope that the CRM bulletin will continue to grow from strength to strength in terms of content as well as impact, in the years to come.

Moving on to 2014, the MOH remains committed to positioning Malaysia as a preferred destination for ISR and as such, I hope that CRM will continue to persevere with its commendable efforts.

Finally, to quote the words of the highly acclaimed astronomer, astrophysicist and cosmologist, Dr. Carl Sagan – "Somewhere, something incredible is waiting to be known".

Datuk Seri Dr S. Subramaniam
Minister of Health Malaysia

DIRECTOR-GENERAL OF HEALTH MALAYSIA

POINT OF VIEW

It is my hope that Malaysians realise the monumental impact clinical research can bring to our lives; it helps deliver better treatments and interventions, improves current therapies and enhances clinical and patient health outcomes. In fact, clinical research goes well beyond that of medical and economic value.

Accelerating clinical research drives medical and support personnel to improve their skills and knowledge in keeping up with ongoing clinical trial requirements, while research centres need to upgrade their equipment and training needs in order to stay competitive. This directly improves the overall standards of the healthcare system as well as patient outcomes, and this in turn will further attract industry interest to conduct more clinical trials in Malaysia.

"It is my sincere hope that these flag bearers will inspire and motivate other therapeutic fields towards similar achievements"

However, increasing the number and quality of clinical research in Malaysia is an uphill task that cannot be achieved overnight. An effective, efficient and reliable ecosystem first needs to be in place to support and facilitate the needs of industry players, the needs of medical professionals, and very importantly the needs of patients. Thus, I am very impressed by the efforts and achievements accomplished by CRM, which was established barely 18 months ago, to drive forward the industry sponsored clinical research (ISR) industry in Malaysia.

I am pleased to note that the 2nd issue of CRM's bulletin places the spotlight on Malaysia's capabilities in the field of cardiology. Indeed, we have a number of truly world-class researchers and institutions that have painstakingly built themselves an international reputation in cardiology related clinical trials. It is my sincere hope that these flag bearers will inspire and motivate other therapeutic fields towards similar achievements.

I am confidently optimistic of the potential contributions that CRM can deliver in the following months and years in making Malaysia a respected destination for ISR clinical trials. However, as is always the case with clinical trials – much remains to be done. In closing, may I say that I believe CRM is up to the task.

Datuk Dr. Noor Hisham Abdullah
Director-General of Health Malaysia

*From the **CEO's** desk*

CRM
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Time has really flown. Guess what…CRM is already 18 months old. I remember back when I was introduced to this entity, it was still a concept, bustling with a plan that is still a 'work in progress'. It was an ambitious attempt, CRM is tasked to bring the country's clinical research, specifically industry-sponsored research (ISR), to the level where Malaysia will be a preferred venue for ISRs. It was indeed a tall order.

How has CRM done? It would be appropriate to analyze the performance of CRM according to the following parameters. The first and foremost is the targeted number of new ISR for the year, the Key Performance Indicator. We have successfully exceeded the targeted number of new ISRs for the year 2012 and 2013. Most importantly are the significant numbers of pivotal trials that we have and are still managing, which may potentially change the current global therapeutic landscape. We have to congratulate the hard work of the Investigators, the efficient management at the site by the Study Coordinators and the whole team at the Headquarters.

The second parameter is increasing the pool of investigators and support team members. Numerous activities were organized, catering to the needs of each segment, and the outcome has been fair. On the Investigator pool, there have been newcomers and some Co-investigators have progressed to be Principal Investigators. The Mentor–Mentee programme, in addition, has resulted in some of the mentees taking up clinical trials. The programme is still in its infancy and needs more time, effort and collaboration to achieve the objective of increasing the number of investigators.

The pace is equally fast on the development of the support team. There has been regular, periodic review of performance and this has resulted in fast track promotion and career enhancement of the team members. We are proud to state that the support team of CRM has begun to gain the confidence of industry players, with some members even being offered jobs within the industry. This is in line with the aspiration of the government of creating higher-value jobs.

Is this what we have aspired for CRM? Surely, there must have been a greater plan. The hypothesis is this: An active industry sponsored research arena would inevitably lead to investigators being roped into the system of clinical research that is regimented, networking with the best in the field, engaging in analyzing trial data, which in entirety sets the research culture. With the advent of this culture, it is hoped that the investigators would initiate their own research, perhaps develop new products or identify new use for existing products, thus creating new intellectual properties. This is the remarkable progression that we as a country want. New innovation in drugs and devices, home grown, that would contribute significantly to the economy of the country.

The endpoints are clear. It is not a unique game plan. It has been tested and proven to be successful in many countries. The challenge is whether we have the will. Are we willing to look beyond local issues? Are we hungry for success? And are we willing to go the long haul?

The clinical research industry is undergoing significant changes. More and more regulations are being put in for greater transparency, for example the need for the industry to disclose the data of trials that shows unfavorable outcome. There are changes seen in the business model, new forms of partnerships are being developed and tested. The collaborations between Contract Research Organizations (CROs) and Pharmaceutical companies are evolving to begin at a very early stage, where the CROs will be involved in the discussion at the stage of product development so as to enable a more focused and efficient clinical trial operation later on.

This changes brings forth new opportunities, presents new ways of cooperation and offers great potentials. As the saying goes, we must "seize the day".

Dr. Mohamed Ali Abu Bakar
CEO, Clinical Research Malaysia

CRM **2013** ISR Statistics

New ISR Approved by IRBs in 2013:

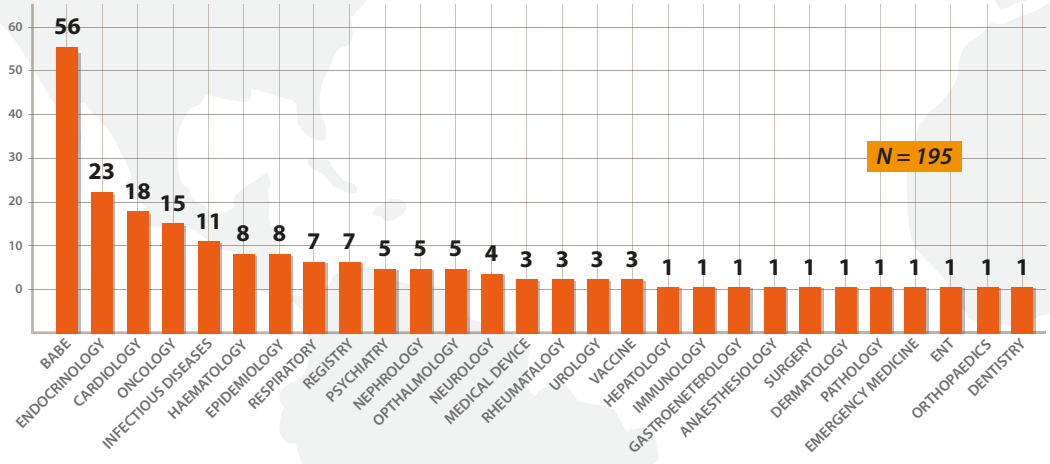
195 trials were approved by the various ethics committees in 2013. These trials were conducted in public hospitals, universities & private hospitals.

IRB = *Institutional Review Board*

New ISR Approved by IRBs in 2013 According to Therapeutic Areas:

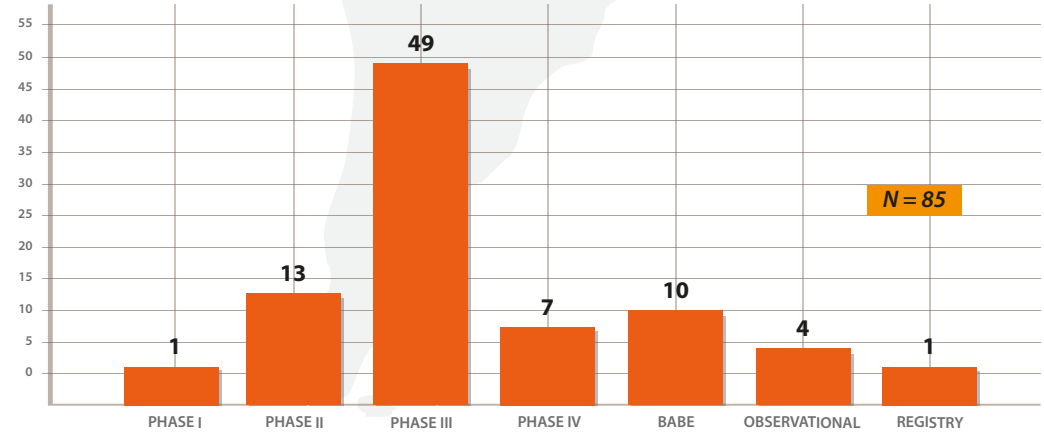
BABE research are the most common with 56 new trials, followed by endocrine, cardiology, oncology and infectious diseases.

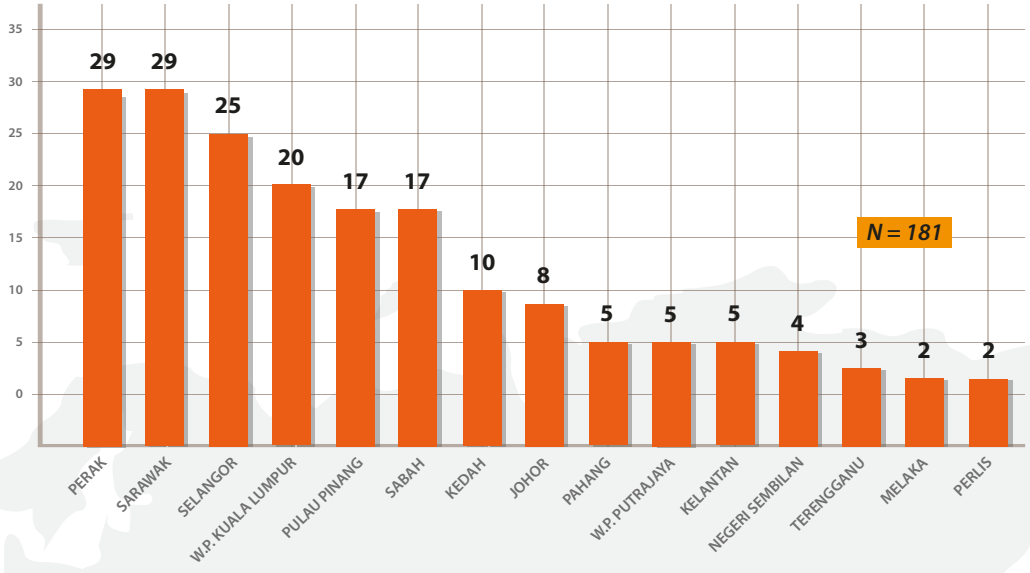
BABE = *Bioavailability and bioequivalence*



Trials Managed by CRM in 2013 According to Phase:

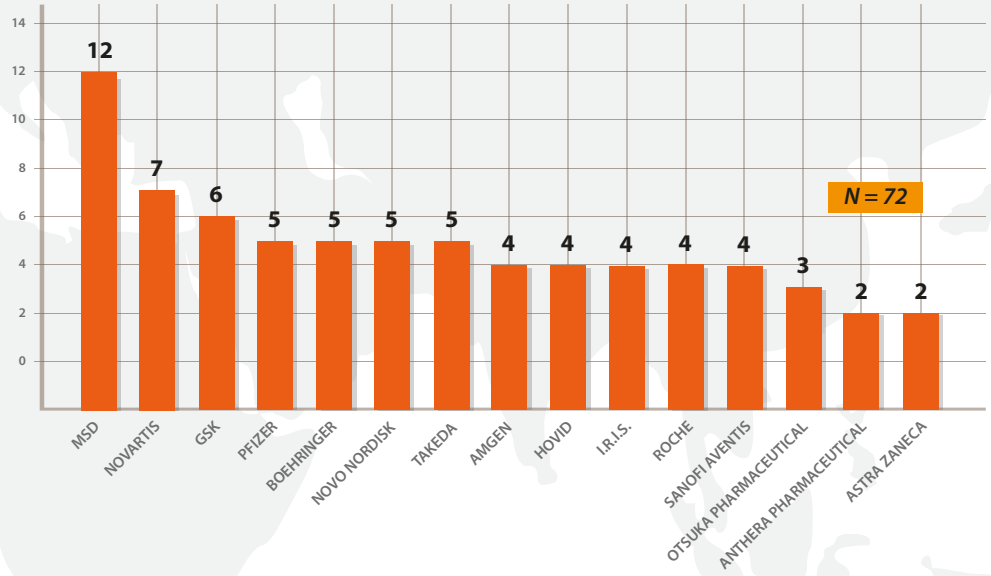
The most common were Phase III trials with 49 studies, while there were only one Phase I trial and one Registry trial.





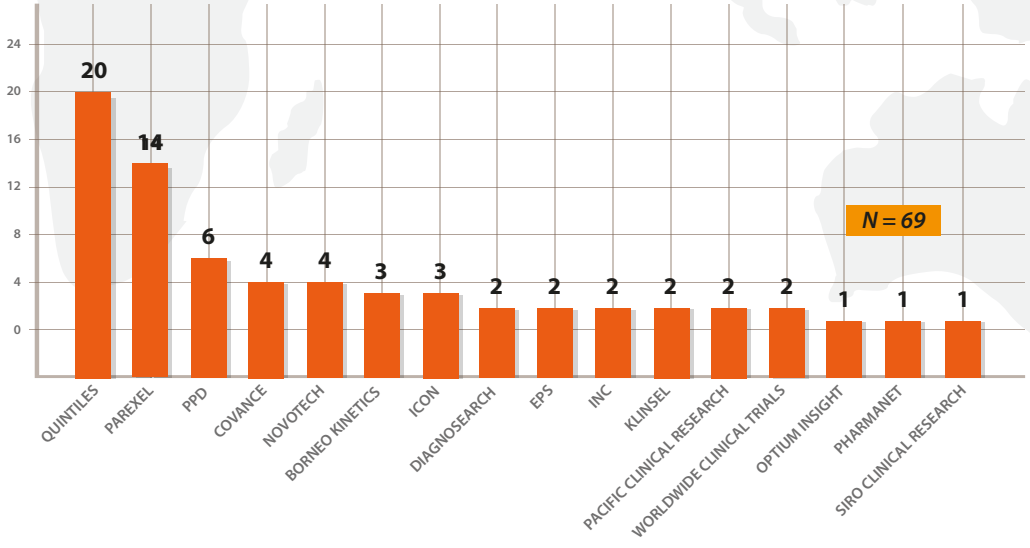
Total Number of Sites with CRM in 2013 According to State:

Perak and Sarawak both had the highest number of trials with 29 each. Melaka and Perlis had the least with only 2 trials each.



Trials in 2013 According to Sponsors:

Merck Sharp & Dohme (MSD) was the most active sponsor in 2013 with 12 trials, followed by Novartis and GSK.



Trials in 2013 According to CRO:

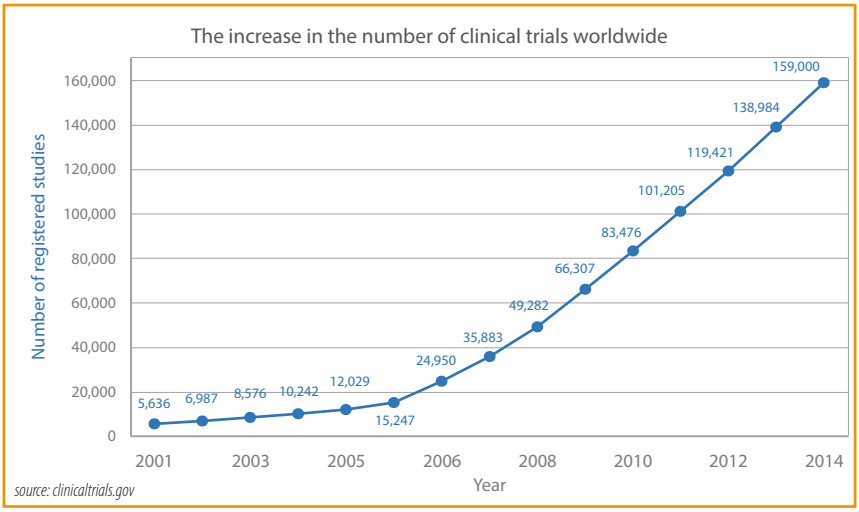
Quintiles was the most active CRO in 2013 with 20 trials, followed by Parexel and PPD.

***CRO** = Contract Research Organization*

Projected Growth in Clinical Trials Globally:

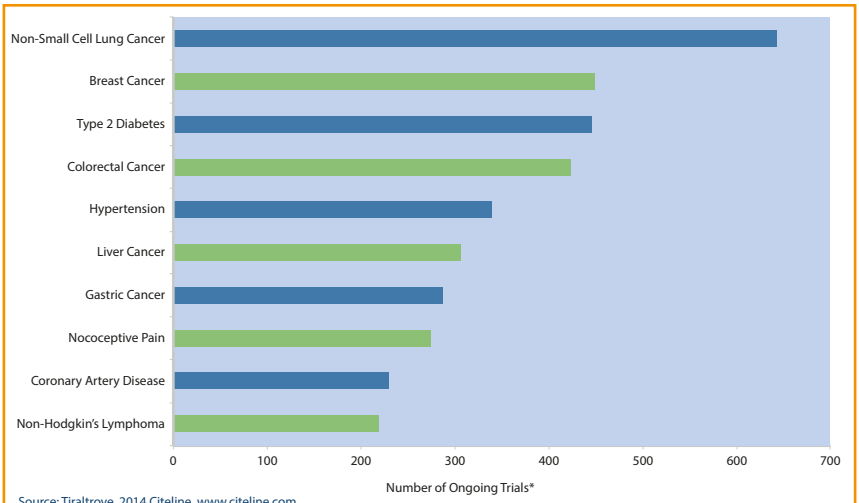
In 2010 there were 83,476 clinical trials registered with clinicaltrials.gov. The number is expected to increase to 159,000 in 2014. The increase is driven by advances in technology, new development areas such as biologics & biosimilars & stem cells, as well as expansion of the CRO industry.

***CRO** = Contract Research Organization*



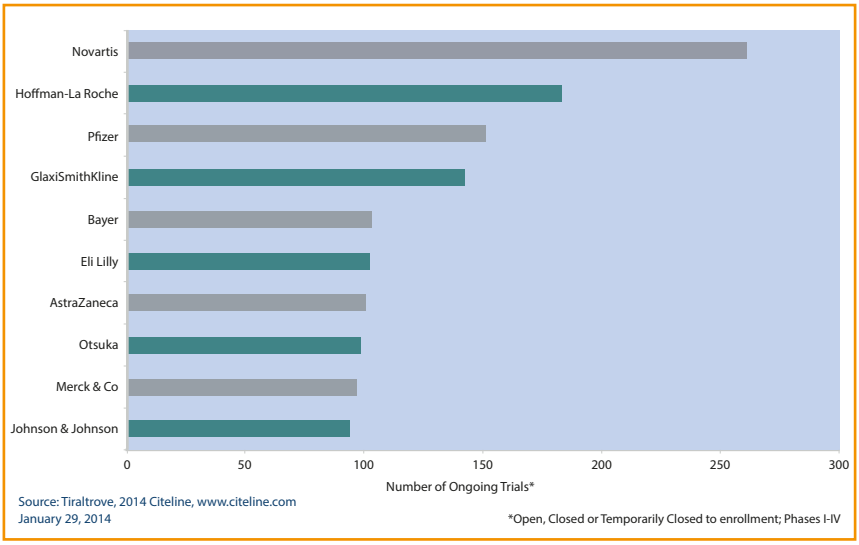
Top 10 Ongoing Clinical Trials in Asia Pacific According to Disease Type:

The largest number of trials in Asia Pacific were for non-small cell lung cancer, followed by trials for breast cancer and Type 2 diabetes.



Top 10 Most Active Sponsors in Asia Pacific:

Novartis was the most active followed by Hoffmann-Le Roche and Pfizer.



Improving the ecosystem for ISR in Malaysia: Towards 1000 trials by 2020

by Communications & Relations Department, CRM

The target set by the Ministry of Health Malaysia (MOH) and the Performance Management & Delivery Unit (PEMANDU) of the Prime Minister's Department is to have 1000 industry sponsored clinical research (ISR) trials underway in Malaysia by 2020. To achieve this goal, the government established Clinical Research Malaysia (CRM) in July 2012 to function as an enabler and facilitator to the industry and medical fraternity, in a plan to boost the attractiveness of Malaysia as an emerging destination for ISR.

The plan has already started to show dividends. The number of new ISR flowing into Malaysia increased by 14% between 2011 and 2012, and posted a further growth of 9% to 195 new trials in 2013. The target for 2014 is to grow the numbers by 15%, or to 224 new trials.

Based on data compiled by CRM, sourced from the Medical Research Ethics Committee (MREC) which manages ethics approval for research to be conducted in MOH hospitals and from 12 institutional ethics review boards (IRBs) that serve research-active private hospitals and universities, the number of ISR new and ongoing trials (trials that had started in a previous year but are still underway) stood at 446 in 2013.

This is still a modest figure when compared internationally - for instance South Korea has more than 5000 ISR trials underway, while Taiwan does more than 3000 and even tiny Singapore boasts about 1200 - but it does indicate a trend of growing awareness and interest amongst medical institutions and the medical fraternity in Malaysia to engage in ISR.

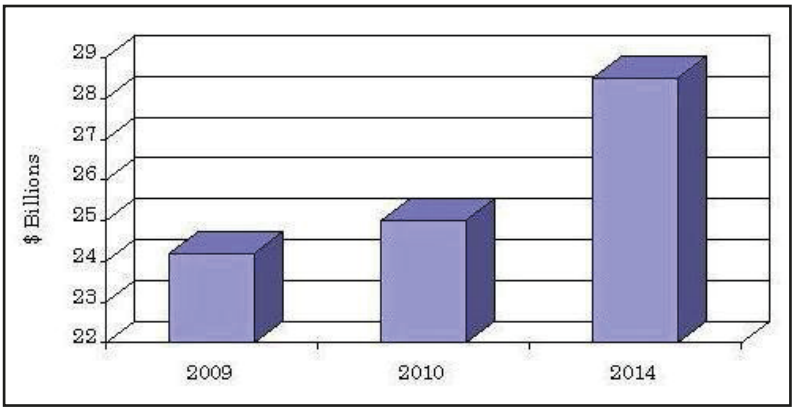
To close the gap between Malaysia and the regional ISR giants, it is vital for the government and other stakeholders to have a "big picture" perspective, in the sense that there needs to be regular evaluation as a whole of the various synergistic components which together form the "ecosystem" for ISR. The graphic below illustrates just some of the key components of this ecosystem.

In an inter-connected environment, existing or potential bottlenecks in one or more areas will soon have a cascading effect on other areas. Thus, a "big picture" approach would generate the maximum gain in the shortest time, as deficiencies or limitations in any part of the ecosystem can be identified and corrected before these cause a detrimental effect on other areas. From another point of view, it would enable the country to advance on a broad front towards achieving its long-term goal of 1000 ISR trials by 2020.

For example, intensive effort and resources spent to promote Malaysia internationally as a good destination for ISR would come to naught, if at the same time, there is a lack of focus to also grow the pool of investigators and support staff, or to improve the capabilities and capacity of sites, or to improve the regulatory mechanisms, or indeed any other component of the ecosystem.

This philosophy of looking at the "big picture" and advancing on a broad front guides the strategies and actions of CRM. To this end, CRM seeks to build strong and beneficial relationships with all stakeholders in the ISR ecosystem.

Implicit in the process of improving the ISR ecosystem is also the necessity for stakeholders to have an understanding of the current trends that are shaping and driving the industry globally. This provides a foundation upon which strategy and action can be formulated, targeted and implemented, in order to keep improving the ecosystem and achieve accelerated progress in attracting more ISR to Malaysia.



U.S. forecast of sponsored clinical trials market, 2009-2014 (US$ billions)

source: bbcresearch.com

Several major trends in play that are shaping the ISR industry this decade are summarized below:

- The increasing costs of drug development are forcing more pharmaceutical companies to outsource their clinical research activities to contract research organizations (CROs). These CROs, some of whom are multi-nationals in their own right, are capable of offering a wide range of services like regulatory consulting, project management, pre-clinical evaluations, study design, clinical trial planning and management, independent safety data monitoring, bio-statistical analysis and many more.

- The outsourcing market itself has evolved into two segments: large sponsors emphasizing partnerships and functional outsourcing with in-house project managers, and small sponsors emphasizing turnkey solutions.

- The ability to operate on a global scale is becoming a necessity for CROs, as it provides them with the opportunity to run clinical trials more efficiently and at a lower per patient cost than in the west. Asia is now their main playing field.

- Another trend is to go paperless and adopt electronic records. A typical new drug application involves hundreds and thousands of paper records. Adopting electronic records has not only made searching and analysis easier, but also improved effectiveness of other initiatives to reduce the costs of development and data management in clinical research. There are multiple technologies that support the electronic data capturing and also the clinical trial management systems for administrative information. E-records also allows for better collaboration across various stakeholders in the clinical processes.

- An emerging trend relates to integrating the data collection, data management, data repository and safety data under one platform along with redefining the business processes and technologies within the organization. The processes of such initiatives are around defining standards for clinical data (metadata). Such initiatives are typically high cost, but provide significant impact on bringing the new drug to the market safely, quickly and cost effectively. It also simplifies safety and clinical data reconciliation, and render post marketing analysis and meta-analysis easier to do.

Professor Dr. Sim Kui Hian

The man at the heart of research

Professor Dr. Sim Kui Hian graduated with an MBBS from Monash University and completed his cardiology fellowship at Monash Medical Centre, Melbourne, Australia. Currently, he holds numerous national and international professional positions including President of the Asian Pacific Society of Cardiology, President of Malaysia Chapter of the American College of Cardiology, Board Member of the World Heart Federation, Visiting Senior Consultant Cardiologist at the Sarawak General Hospital (SGH) Heart Centre, Advisor of Clinical Research Centre (CRC) SGH, and was the immediate Past President of the National Heart Association of Malaysia. He is also a member of the Hospital Visitor Board of SGH and a board member of Clinical Research Malaysia (CRM).

His research interests include cardiac computed tomography (CT), cardiac magnetic resonance imaging (MRI), antiplatelet, metabolic syndrome and acute coronary syndrome (ACS) biomarkers. With over a decade of experience in cardiology and clinical research, CRM was most honoured to have the opportunity to interview the highly renowned heart specialist and researcher who founded the Clinical Research Centre at the SGH. Following are excerpts from the interview:

You ventured into clinical research in Malaysia at a time when Malaysia was not ready to be a centre for clinical trials. Could you tell us how you got involved in clinical research and where did Malaysia stand in terms of industry-sponsored research (ISR) during your early working years?

I was involved in clinical research during my cardiology training stint at the Monash Medical Centre in Melbourne. When I came back to Malaysia in 1998 after 17 years in Australia, I had a hard time convincing the major clinical research industry players of our ability to conduct clinical trials locally because we did not have any previous track record. Being unable to secure a collaboration with multinational drug companies, my colleagues and I started on a few small clinical trials despite several hiccups along the way.

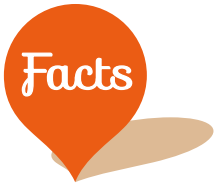
During a discussion with several sponsors in 1999 and 2000, I requested the help of my Australian counterparts to convince the sponsors that we were capable of carrying out clinical trials in Penang, where I was based at that time. Building on the experience we had in conducting clinical research locally and the opportunity given by several drug companies, we managed to build up our credentials. Along the way, other companies and contract research organizations started to approach us with new clinical trials.

How many trials have you conducted so far?

At least 100 multi-centre clinical trials in Malaysia and abroad. In more than 50 of these trials, I was the Principal Investigator (PI), and in more than 20 trials I became the country or regional PI.

Do you mainly conduct ISR?

Most of the trials that I have conducted are industry-sponsored. During those times, we did not have a trained team of clinical research physicians, nurses and study coordinators. We also lacked the knowledge, experience and expertise in developing clinical trial protocols, design and statistics, as well as GCP compliance for our staff and all the other supporting facilities such as a –80 °C refrigerator. Unless the research is in public health or conducted in a university, support from the Ministry of Health for clinical research at that time was insufficient. We realised that if we wanted to conduct our own trials, it was best to collaborate with the ISR players as they can provide training to our research team and handle all the legal and administrative work.



Eighteen ISR trials in cardiology were conducted in Malaysia in 2013. These include trials on familial hypercholesterolemia, pulmonary arterial hypertension, essential hypertension, and coronary artery disease.

Are all your trials related to cardiology?

Yes, and this includes trials on lipids, high blood pressure, diabetes, antiplatelets and cardiovascular devices such as coronary stents.

Is there any trial which you particularly remember?

There are just too many to recall. Most of the clinical trials that I had participated in were published in reputable international journals. However, I am particularly proud to have co-authored two clinical trials which have been published in the New England Journal of Medicine (which had the highest impact factor among general medical journals in 2012). Being able to document my name in renowned medical journals is testament of my team's hard work and recognition in the medical field, despite being from the jungles of Borneo.

Did you face any difficulties recruiting patients?

Not really. However, I believe that this issue is not so much about the number of patients an investigator recruits, but more on how capable he/she is in leading and managing the trials. And that can only come through on-the-ground experience and definitely not sitting in an ivory tower.

Most doctors do not have the time to be involved in clinical research as they feel that clinical work takes up too much of their time from their daily clinical practice. What is your take on this?

I believe that it is just a matter of whether you want to do it. If it is something that you do not want to do, having 72 hours in a day won't be enough to get the job done. On the contrary, if it is something that you want to do, the job can be completed even if you only have 12 hours in a day.

Are you still involved in clinical trials?

If I am around in SGH Heart Centre, I still do. If not, I have a team to run them for me. Clinical trials is not a one-man show. We need to have a team of people that are contactable 24/7. Patients must be assured that if anything happens and I am not around to deal with them, my team mates are there to provide assistance.

How big is you team and was it difficult to get people to join your research team?

About 10 cardiologists. Here in SGH Heart Centre, we adopted clinical research as part of our department's activities, thus making it a culture whereby everyone participates in it.

Did you always wanted to become a doctor when you were young?

Not really. My father was the youngest of 7 brothers and none of my family members and relatives were doctors. Hence I wanted to be different and be the first doctor in the family.

Okay, but why cardiology?

I lived in Australia for 17 years. I was six months short of completing my specialisation in intensive care when two of my good friends who were cardiologists asked me to specialise in cardiology so that we could meet up once a year at international meetings. That was how I ended up in this field. So, you see, no one is born with their destiny stamped on their forehead. No one knows what the future holds.

Towards fixing damaged hearts through tissue engineering

In the US, someone suffers a heart attack every 34 seconds -- their heart is starved of oxygen and suffers irreparable damage. Engineering new heart tissue in the laboratory that could eventually be implanted into patients could help, and scientists testing with rat cells are reporting a promising approach.

Source: McMurray JJV, Gerstein HC, Holman RR, et al. (2014)

Prof Dr. Sim with CRM & CRC Sarawak staff.

You are married with two children. How supportive is your family and do you find time for any hobbies?

My wife has been working alongside me during our training stint in Monash and understands the nature of my work. When my son was younger, he used to tell his friends that his dad is a doctor but works in an airport; simply for the fact that I was travelling so often. There is hardly any time for myself having to juggle between clinical service, hospital and NGO activities, research and politics.

What do you think are the common challenges in promoting clinical research among medical professionals in our country?

The window of opportunity for conducting clinical research in Malaysia is very small because we are seen as a glass half full. Clinical trials have been gaining momentum and becoming competitive in the last few years, with China and India becoming a favourable destination for clinical trials bolstered by their ability to conduct fast and cheap trials. If we do not upgrade our skills and capabilities, once these countries become the major players in clinical research, our services might not be needed anymore.

In your opinion, why do you think many medical professionals are not interested in clinical research?

It all boils down to having passion and enthusiasm in clinical research. Equally important is the realisation that clinical research is a reflection of one's clinical practice and a platform to be recognised internationally.

Having conducted so many industry-sponsored clinical trials, do you think Malaysia has the potential to become a centre for ISR?

There is no reason why we cannot achieve it. But if we do not move with the emerging research industry giants (China and India), we will definitely be left behind.

You are currently the President of Malaysia Chapter of the American College of Cardiology, President of the Asian Pacific Society of Cardiology (APSIC), Board Member of the World Heart Federation and on the Executive Committee of the Asian Society of Cardiovascular Imaging. What advice would you like to give to our young and budding medical professionals?

Well, generally if you want your efforts and contributions to the medical industry to be recognised by the international community, involvement in research is the only way to go. Very rarely can clinical service alone place you in the international spotlight. At the end of the day, passion, perseverance, hard work and teamwork are the recipe for a successful career in clinical research.

"If you want your efforts and contributions to the medical industry to be recognized by the international community, involvement in research is the only way to go"

The First *Bioequivalence Study* in *The Land Of The Hornbills*

by Yanti Nasyuhana Sani, Head of Bioequivalence Programme, Clinical Research Centre, Sarawak General Hospital

The all-Malaysian CRC bioequivalence team.

Saturday 2nd March 2013 was a historic day for Clinical Research Centre (CRC), Sarawak General Hospital (SGH), as the first bioequivalence (BE) study was finally conducted here under the supervision of two visionary leaders, Prof Dr. Sim Kui Hian and Dr. Alan Fong. The fully equipped CRC Research Ward which is located in Kota Samarahan (about 15 km from the main SGH) boasts world-class facilities and has an all-Malaysian CRC team led by Dr. Alan Fong. The CRC team consisted of more than 30 Ministry of Health (MOH) staff, including pharmacists, nurses, scientific officers and doctors.

The implementation of the first BE study was successfully executed via partnership with a local contract research organization (CRO), Borneo Kinetics Sdn. Bhd. This study was conducted to compare the rate and extent of absorption of a generic oral dosage form of 80/400 mg Trimethoprim and Sulphamethoxazole manufactured by Pharmaniaga under the brand name Co-trimoxazole. It took three weeks for completion, starting from pre-screening of healthy volunteers to safety assessment. With the kick-off of the first BE study, the National Pharmaceutical Control Bureau (NPCB) audited this newly established BE Centre to ensure that the study complied with the conduct of Good Clinical Practice (GCP).

The setting up of a dedicated facility for CRC SGH began around September 2008. During that time, it was envisioned that a BE unit would be incorporated into the new CRC block. This first fully integrated clinical research facility in the country was aimed to spearhead the drive for clinical research, especially early-phase research. The responsibilities of setting up the BE unit in CRC SGH were given to two pharmacists, Miss Yanti Nasyuhana Sani and Miss Tiong Lee Len, who were under the supervision of a regulatory body in the NPCB and Prof. Yuen Kah Hay, a BE expert from Universiti Sains Malaysia (USM).

Under the strong leadership of the head of CRC SGH, Dr. Alan Fong, not only does the BE unit comprise of a highly skilled research team, but also an advanced lab and clinical facilities. This, in part, contributed to the success of the first BE study. The facilities include a 24-bedded ward (expandable if required) that is well-equipped for clinical trial activities, a sample-handling laboratory with a refrigerated centrifuge, refrigerators and freezers (–80°C and –20°C) for blood plasma storage, a temperature-controlled drug storage area affixed with a close-circuit television, 6 synchronised digital clocks, an archive room with controlled access and free wi-fi. Of importance is the availability of a 4-bedded room with intensive care settings to ensure proper care of subjects who may require emergency treatment or other medical care.

CRC SGH had successfully set up the first BE unit in Malaysia which is situated within a tertiary referral hospital. Researchers at this centre are now ready to participate in the development of safe and effective generic drugs through partnerships with the MOH as well as local and international pharmaceutical companies. We hope that our BE centre will be recognized and listed in the NPCB Compliance Programme for Bioequivalence Centre. In the long run, we are looking forward to becoming an internationally-recognised centre to perform BE studies, apart from providing independent clinical and analytical services to the MOH. Our mission is to develop a world-class BE programme and service, while still adhering to our core values – teamwork, professionalism and patient-centred care. In the spirit of Malaysia Boleh, we will strive for excellence in our services to meet ethical, regulatory, scientific and specific needs of our clients.

The challenge of patient recruitment in Asia

by Tarun Pandotra, Project Manager of PPDi Singapore

Recruitment and *retention* of research participants are often the most labor-intensive and difficult component of clinical trials. Poor recruitment and retention frequently pose major barriers in the successful completion of clinical trials. In fact, many studies are prematurely terminated, or their findings questioned due to low recruitment and retention rates.

Achieving adequate clinical trial research participant enrollment is essential to conducting a successful trial. Adequate enrolment provides a base for projected participant retention, resulting in evaluative patient data. Without sufficient patient retention from the time of study initiation to closure, it may be too small a pool for conclusive proving or disproving of the goals.

> *"Patient recruitment and retention are often major challenges in clinical trials"*

For more than a decade, the emerging markets of the Asia Pacific region have held special promise for the global pharmaceutical industry. Driven by a combination of low per capita consumption, rapidly expanding economies, technological innovation and a talented workforce, the region has seen explosive growth in both economic and political power during the past 10 years. Today, China and India stand on the threshold of being global superpowers, while a range of factors such as deregulation, better trade links, improved access and rise in medical tourism have enabled markets such as Malaysia, Vietnam, Indonesia and others to take on increasingly important roles in the region.

Recruitment is approached as a separate process from the research protocol. Lack of collaboration between the principal investigators (PI) and research coordinators perpetuates the problem because the criteria for entry into a trial are often so exclusionary that it makes recruitment even more challenging. Lack of follow-up systems contribute to losing patients before they have completed a trial. For example, many trial sites do not follow up with participants to let them know when the trial has ended, or the results of the research and the contribution it made to medical knowledge.

We probably do our worst when it comes to retention and the acknowledgement of the valuable contribution that a volunteer makes. There is a lot of data showing that once the patient has participated in the trial and they are familiar with the professionalism and integrity of the research system, they become ambassadors and can play a valuable part as a member of the public in helping to shape an understanding of this enterprise and its value. And we do that with a number of different kinds of programs.

You have many studies today that will offer thank you cards or that will have a special gathering at the end of the study, but it is not enough. A large percentage of patients, roughly 80 percent of patients in clinical trials, will say that they would like to know the value of the contribution they made. They want to know whether it made any contribution to knowledge in medical science. And yet 79 percent of all volunteers who have completed enrolment never hear from the site again.

Often the patient directs their concern to the PI or the study coordinator. These individuals have their hands tied as well, especially when it is an industry-funded study. The investigator has no additional knowledge, so there is a gap when the volunteer wants to know about their contributions and the research staff cannot provide the information.

Asian countries have also started facing challenges in recruitment and retention of patients. This is a time of considerable change in clinical research. It is getting more difficult to recruit patients for many reasons.

The challenges:

- About 65–70 percent of the patients in Asian countries live in rural areas where hospital infrastructure does not support clinical research.
- Low awareness of opportunities to participate in clinical trials.
- An ageing population that takes drugs for multiple chronic conditions, which makes them ineligible for most trial protocols.
- Public concern over safety of new medications in the wake of major drug recalls.
- Use of herbal medicines.
- Scepticism about trials designed only to expand the market for a drug to include an additional condition.
- Concentration of trials at academic medical centres that are out of geographic reach of many Asians.
- Delayed start-up, inadequate planning, insufficient effort and staff, high expectations, lack of willingness to go against personal physician and insurance or cost problems.
- An industry that focuses on trial protocols without a strategy for how to fill the trial.
- The lack of economic incentive for physicians to refer patients to trials or to conduct trials themselves.
- Widespread fatigue and resignation among professionals that the difficult recruiting situation cannot be resolved without major overhaul of the healthcare system.
- The financing system that few believe is realistic.

It is time to call for nothing less than a complete overhaul of the recruiting process to focus squarely on the patient and redefine the way we look at clinical trials, as if we were the patient.

This would lead to:

- A greater focus on communicating with volunteers about the larger contribution they make to medical advances by participating, and sharing the results of research accordingly.
- Promoting the opportunity to receive state-of-the-art care and then providing it consistently.
- Offering the convenience of staying in the community practice while participating in research.
- Providing patients access to their own records as well as overall trial data online so they feel part of the progress.
- Creating online support networks for participants.

**Article reprinted with permission from BioSpectrum Asia.*

PINK RIBBON
Wellness (L) Foundation

Let's paint the town pink!

Are you a breast cancer survivor? A care giver perhaps? Or a healthcare professional involved in the research, treatment, management and care of women with breast cancer? In fact, if you are just interested in joining the fight against breast cancer, then, come, join us and save the date!

Pink Ribbon Wellness (L) Foundation together with Clinical Research Malaysia as co-organiser, is pleased to welcome you to the 'Life Beyond Breast Cancer-2nd International Symposium'. In the fight against breast cancer, Pink Ribbon Wellness (L) Foundation is dedicated to empowering women with knowledge on breast health, advocating preventive measures, encouraging regular breast screening and providing supportive care for survivors.

We will be flying in international as well as national speakers to present a variety of interesting topics ranging from nutritional guidelines, to recent updates on breast cancer therapy, to discussions with the experts in the field of breast cancer. It will be a three day event where you will be able to participate in a series of workshops covering multiple aspects of breast cancer survivorship.

We are thrilled to organise this symposium and hope that it will provide a powerful and inspiring opportunity to unite as a community to honour breast cancer survivors, to exchange views on breast cancer survivorship and to raise awareness of the need for regular screening to meet the vision of the Breast Cancer Deadline 2020, which is to end the disease by the end of the decade.

Together, let us take strides towards a breast cancer-free future for our loved ones.

GOOD CLINICAL PRACTICE:
Certified Investigators Ensure Quality of Clinical Trials in Malaysia

by Dr. Lil Edis, Regional Director (Asia) at Novotech, Australia

The clinical trials landscape in Malaysia is very easy to navigate. The Malaysian government has been actively promoting clinical trials and other facets of biomedical development for many years now, with investments in research, infrastructure, support organizations and promotional activities. There are over 30 established investigator sites in Malaysia and an active clinical research center (CRC) network.

Most investigator sites have dedicated study coordinators and the medical records are in English. Any clinical trials conducted at government hospitals must be registered on the National Medical Research Register (NMRR) and is published in the Directory of Medical Research on the NMRR website. Furthermore, details about all principal investigators are published in a directory of clinical investigators and medical researchers on the NMRR website, therefore enabling sponsors to readily identify potential investigators and competing trials.

Over the last decade, the number of industry-sponsored multinational trials commenced in Malaysia, fluctuated greatly; although the proportion of trials in the country relative to the rest of the Asia Pacific region remained fairly constant, with a low of 10 percent in 2011 and a high of 19 percent in 2007.

Malaysia has a population of 30 million, which is ethnically diverse, and there is a high prevalence of 'first world' diseases. Coronary artery disease (CAD) is the largest single cause of death in Malaysia, and the government sees Type 2 diabetes as the most significant health issue. There were 10 industry-sponsored multinational clinical trials on new treatments for CAD that commenced in the Asia Pacific region between January 2012 and August 2013, and eight (80 percent) of these included investigator sites in Malaysia. During the same period, there were 59 industry-sponsored multinational clinical trials on new treatments for Type II diabetes, and 21 (36 percent) of these included investigator sites in Malaysia. In contrast, there were 117 industry-sponsored multinational clinical trials on new cancer treatments, but only 13 (11 percent) of these included investigator sites in Malaysia.

Investigators in Malaysia are enthusiastic towards participating in sponsor-initiated clinical trials and the early access to new medicines that this affords. However, they are generally least willing to participate in clinical trials of medicines to treat rare diseases. The return on investment is too low in terms of number of potential subjects versus the time commitment.

"Malaysia has a high incidence of first-world diseases, transparent review processes, short start-up timelines, lower financial costs and experienced investigator teams delivering high quality clinical research"

Similarly, it may not be feasible to conduct clinical trials of certain classes of drugs such as opioids and amphetamines in Malaysia or neighboring countries, because they are not as widely prescribed as in other parts of the world. Also, if the clinical trial eligibility criteria require that subjects must have received prior treatment with expensive medicines such as biologicals, potential subject numbers will be limited because the medicines are not sufficiently subsidized by the government and relatively few patients in Malaysia can afford them.

Due to population size and overall health-spend, the potential for medicine sales in Malaysia is very small compared with many other countries in the Asia Pacific. Unlike India, China, South Korea, and Taiwan, there are no regulatory requirement to include local patients or to conduct clinical trials in Malaysia in order to gain marketing approval in the country.

The financial costs associated with conducting clinical trials in Malaysia is very competitive. The institutional review boards (Ethics Committees) and regulatory approval processes in Malaysia are conducted in parallel and are quite straight forward. Submission dossiers can be in English (with the exception of subject materials such as informed consent forms which also need to be in Chinese and Malay) and there is a central ethics committee (Medical Research Ethics Committee) which covers all government hospitals and which meets every fortnight. The time-lag between ethics committees and regulatory dossier submission and investigator site initiation in Malaysia is typically less than three months. In contrast, in China and India, the time-lag and processes are not only very much slower, but also inconsistent and unpredictable.

Although there is no national template for clinical trial agreements (CTAs), the process for review and sign-off of CTAs in Malaysia is quite fast compared to other countries in the Asia Pacific. On the other hand, sponsors can expect to pay a CTA review fee of up to US$1,200 (about RM4,000). One of the most convincing arguments for conducting clinical trials in Malaysia is quality. Not only is it mandatory for investigators in Malaysia to hold Good Clinical Practice (GCP) certification, the certification can only be obtained by attending a three-day Ministry of Health-approved workshop and then passing a formal exam. In Malaysia, the majority of investigator site staff are GCP-certified, so are most clinical research associates in the country.

To sum up, Malaysia has a high incidence of first-world diseases, transparent review processes, short start-up timelines, lower financial costs, and above all, experienced investigator teams delivering high quality clinical research.

**Article reprinted with permission from BioSpectrum Asia.*

2014 GCP workshops organized by CRM

Opening speech by Dr. Mohamed Ali, CEO of CRM

The participants

GCP exam in progress

Research Personality

Tan Sri Dato' Seri Dr. Robaayah Zambahari

MD & CEO of National Heart Institute

Spearheading IJN into a world class cardiology centre

Malaysia's premier heart centre, the National Heart Institute or most commonly referred to as Institute Jantung Negara (IJN), receives cardiology cases referred from all over the country and abroad. Since its establishment in 1992, IJN has kept abreast with the latest medical advances and remains the leading heart-related medical institution in the region. Part of IJN's success is derived from the numerous multi-centre international clinical trials that are conducted there, many of which positively impact the clinical practice of medical professionals.

At the heart of IJN is Tan Sri Dato' Seri Dr. Robaayah Zambahari, its Chief Executive Officer and Managing Director, and a Senior Consultant Cardiologist. Tan Sri Dr. Robaayah believes that she has one of the best jobs in the industry – pursuing research, performing life-saving operations, and shepherding IJN as the leading heart centre in the region. Following are excerpts of the interview with her.

> "I have one of the best jobs in the industry – pursuing research, performing life-saving operations, and shepherding IJN as the leading heart centre in the region"

Could you tell us what was the first clinical trial that you conducted?

That would be the ACUTE II (Antithrombotic combination using tirofiban and enoxaparin) trial which was published in the American Heart Journal 2002. It was tough as we had to juggle between conducting our first ever trial and clinical practice. We started recruiting patients in 1997 and I could vividly remember Dato' Dr. Rosli Mohd Ali and Datuk Dr. Razali Omar as co-investigators and Ramayee as the study coordinator. Along the way, we learned the processes involved in clinical trials. There were 525 patients and 54 participating study sites. Our peak of excitement and satisfaction came when our manuscript was accepted by the American Heart Journal and seeing our names and institution in print – even though it only appeared in the Appendix! But that set the precedent for many more similar trials involving cardiovascular drugs and devices, particularly stents.

What would you consider to be your biggest research achievement?

While it is difficult to say what was the 'biggest' research achievement, I consider two types of trials as particularly 'special'. The first type of trial is one that had a major impact in clinical practice. For example, the PLATO Study which investigated ticagrelor versus clopidogrel in patients with high-risk acute coronary syndromes. This study found that ticagrelor significantly reduced the rate of death from vascular causes, myocardial infarction or stroke as compared with clopidogrel.

The second type of trial is one where we conducted a first-in-man trial. For example the REMEDEE Study which demonstrated the safety and effectiveness of the Combo Bio-engineered Sirolimus Eluting Stent compared to the commercially available TAXUS® Liberté® Paclitaxe-Eluting Stent in the treatment of single de novo native coronary artery lesions.

Facts

Since the inception of IJN in 1992 to the end of 2013, more than 2.6 million outpatient and 238,453 inpatient visits were recorded. During the same period, 146,031 invasive procedures and 59,674 surgeries have been performed, and this included cases of paediatric congenital heart diseases.

How do you lead and motivate your research team?

We have a strong research team with a clinician as director, a senior manager and a number of clinical research assistants (CRAs). We take the effort to keep in constant communication, encourage and guide the CRAs on the ways to conduct and lead research projects (be it an investigator-initiated trial, an industry-sponsored trial or in collaboration with higher education centres and pharmaceutical companies). My team and I have also gone the extra mile to create a conducive ecosystem to support research activities; this include ensuring a well-trained study coordinator to oversee the division of work amongst the CRAs, to facilitate data collection, data processing and activities throughout the study period. Finally, I believe that every individual's contribution to the research project and to the team should be acknowledged as it serves as part of the motivational process.

How do you ensure that your clinical trials are of high quality and run smoothly?

We make sure that all equipment necessary for the study are available and well-maintained in accordance with national and international guidelines. For research projects that require funding (especially investigator-initiated trials), research funds can be applied from the Institut Jantung Negara Foundation (IJNF) as well as from special grants from the government. Equally important is for the research team to follow basic training in Good Clinical Practice (GCP), attend regular on-going training with didactic lectures and workshops. The research team are also given opportunities to attend local and regional conferences and workshops that are related to the proper conduct of research projects.

How has the research culture evolved in IJN over the past decade?

Clinicians and allied health personnel have become more aware of the importance and significance of conducting research in the clinical field, to help answer hypothetical clinical questions, to look at clinical trial data critically and meaningfully, to understand the limitations of the trial results and to apply the results accordingly for the safety and benefit of patients.

IJN established the Clinical Research Department in 2004 to support clinicians and allied health personnel in conducting research projects. The Institutional Ethics Committee was also established to ensure all research projects conducted here comply with the International Conference on Harmonization-Good Clinical Practice ICH-GCP to ensure that the well-being of trial subjects are protected.

To ensure that the relevant staff who are involved in research projects are well-trained, IJN has conducted in-house GCP workshops since 2008. This in-house GCP workshop is a collaborative effort by IJN and Cyberjaya University College of Medical Sciences (CUCMS), and is conducted by an established researcher, Prof Dr. Abdul Rashid Rahman.

How has clinical research improved the function and services of IJN?

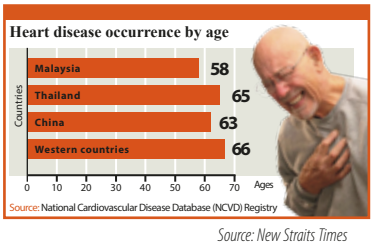
I believe that participation has improved our knowledge on the conduct, interpretation and the limitations of clinical trials. As such, we are able to apply best practice in the day to day management of our patients. By participating in clinical trials involving devices and technology, we are able to get first-hand experience in understanding the safety and efficacy of these products, again empowering us to apply our knowledge in managing our patients. Besides, earnings from clinical research projects can be utilized as study grants to encourage clinicians to embark on in-house research projects, which can lead to improvement in the treatment of our patients.

IJN successfully implants smallest pacemaker device in patients

The National Heart Institute (IJN) has successfully implanted four of the world's smallest pacemaker device, the Medtronic MICRA Transcatheter Pacing System (TPS), in patients suffering from bradycardia (slow or irregular hearbeat). Its senior consultant cardiologist and electro physiologist, Datuk Dr. Razali Omar said this was done after IJN was chosen as the first centre in Asia Pacific to participate with Medtronic Inc., the world's largest maker of medical devices' global clinical study. The MICRA TPS is one-tenth of the size of a conventional pacemaker, and comparable in size to a large vitamin.

Source: ABN News (March 2014)

Facts



Source: New Straits Times

What would be your advice to aspiring clinical trial researchers?

Fundamentally to be a good clinician today, we need to practice evidence-based medicine. To do so, we need to keep abreast with the latest scientific knowledge and progress relevant to our field with a view towards improving patient care and outcome.

The most practical way to start one's career in clinical research is to be part of a research project team – to learn from a senior mentor i.e. the principal investigator of the project on the various aspects of a clinical trial – formulating research question, study design, preparation of protocol and submission for grant application, understanding issues related to ethics and regulatory principles that govern trials in human subjects, practical operational matters such as recruitment of subjects, data collection and analysis, managing finances and personnel in the research team, and finally preparation of materials and manuscript for presentation or publication.

Apart from this practical 'apprenticeship' in clinical research, the aspiring researcher needs to equip himself/herself with the relevant knowledge on the principles of clinical research and trials, bio-statistics as well as ethics and research management by attending formal courses on research methodology, bio-statistics and obtaining GCP certification.

Industry Development & News

Discrepancies in clinical trial reporting raise questions of accuracy

In an analysis of 96 research trial results published in top journals, almost all had at least one discrepancy between what was reported on the public clinical trial registry, clinicaltrials.gov, and what was posted in the journal article. A new research letter raises serious questions about the accuracy of results reporting in both clinical trial registries and publications, and the importance of consistent presentation of accurate results.

Source: Becker JE, Krumholz HM, Ben-Josef G, et al. (2014)

Many trial results in clinicaltrials.gov not published

The trial registry clinicaltrials.gov, which permits posting of trial results, includes results of some trials that have not been published in a peer-reviewed journal and in some cases includes more information than published trials. The authors that conducted this study acknowledge that unpublished trial results could be published at a future date; some trials may be submitted for publication several years after completion.

Source: Riveros C, Dechartres A, Perrodeau E, et al. (2013)

Biases in animal studies may differ from those in clinical trials

A new analysis of animal studies on cholesterol-lowering statins led by Lisa Bero, UC San Francisco found that non-industry studies had results that favoured the drugs even more than studies funded by industry. In previous studies, Bero determined that drug-company-sponsored clinical trials were associated with publication of outcomes that favour the sponsor. Bero's work has been cited as part of policy reform efforts that have led many journal publishers, agencies and institutions to require researchers to disclose funding sources and possible conflicts of interest when presenting their research.

Source: Krauth D, Anglemyer A, Philipps R, et al. (2014)

Unpublished trial data 'violates an ethical obligation' to study participants, say researchers

Almost one in three (29 %) large clinical trials remain unpublished five years after completion. And of these, 78 % have no results publicly available, finds a new study. This means that an estimated 250,000 people have been exposed to the risks of trial participation without the societal benefits that accompany the dissemination of their results, say the authors. They argue that this "violates an ethical obligation that investigators have towards study participants" and call for additional safeguards "to ensure timely public dissemination of trial data".

Source: Jones CW, Handler L, Crowell KE, et al. (2013)

Latest in Cardio Trials

New blood test can detect heart attacks more quickly

A new blood test can detect heart attacks hours faster than the current gold-standard blood test, a study has found. Between 60 % and 70 % of all patients who complain of chest pain do not have heart attacks. Many of these patients are admitted to the hospital, at considerable time and expense, until a heart attack is definitively ruled out. An electrocardiogram can diagnose major heart attacks, but not minor ones. There also are blood tests for various proteins associated with heart attacks, but most of these proteins are not specific to the heart. The new test measures a protein that is released to the bloodstream by dying heart muscle, and has the potential to save lives by guiding treatment much earlier than is done with current testing methods.

Source: Martins AM, Eng G, Caridade SG, et al. (2014)

Novel marker, possible therapeutic target for cardiovascular calcification identified

Cardiovascular calcification (deposits of minerals in heart valves and blood vessels) is a primary contributor to heart disease. While there currently is no medical treatment for this condition, a team of researchers has discovered certain proteins in osteoclasts, a precursor to bone, may be used in helping to destroy cardiovascular calcification by dissolving mineral deposits. This research suggests a potential therapeutic avenue for patients with this condition.

Source: Itou T, Maldonado N, Yamada I, et al. (2013)

Heart risks of glucose-lowering drugs being overlooked in clinical trials

Hospitalisation for heart failure is one of the most common and prognostically important complications of diabetes, a new review indicates. Moreover, increasing evidence shows that some glucose-lowering drugs increase the risk of heart failure. Yet, heart failure is rarely considered as a key outcome, or even part of composite cardiovascular outcomes, in clinical trials of glucose-lowering drugs.

Source: Thibodeau JT, Turer AT, Gualano SK, et al. (2014)

2013 Year in Photos

Mentor-Mentee Northern Region 2013

Mentor-Mentee Central Region 2013

APHM International Healthcare Conference & Exhibition 2013

Diabetes Asia 2013 Conference

BioMalaysia 2013

Negeri Sembilan Research Day 2013

Terengganu Research Day 2013

Kelantan Research Day 2013

TigerMed (China) Delegates Visit

CRM presentation to Heads of Departments at Hospital Raja Perempuan Zainab II, Kelantan

CRM 2013 Strategic Planning Retreat

Publish in the CRM bulletin

We welcome submissions of feature articles, write-ups and events related to industry sponsored clinical research for publishing in the CRM bulletin, which is issued quarterly. You can send your submission to contact@clinicalresearch.my or contact us at +60 3 7960 5153 should you have any queries.

2014 UPCOMING NATIONAL & INTERNATIONAL EVENTS

National
International

APRIL

- World Ophthalmology Congress (2nd – 6th, Tokyo)
- Cardiovascular Updates for Doctors & Allied Healthcare Professionals Symposium (5th – 6th, Kuala Lumpur)
- 6th Annual Asian Oncology Summit (11th – 13th, Kuala Lumpur)
- APAGE Clinical Forum on Inflammatory Bowel Disease (18th – 19th, Penang)

MAY

- Diabetes Complications Conference & Grand Rounds (9th – 11th, Kuala Lumpur)
- 4th Borneo Infection Control Congress (15th – 16th, Kuching)
- Penang Research Day (23rd, Penang)
- The 14th Asian Pacific Congress of Nephrology (14th – 17th, Tokyo)
- The 2nd Asia Pacific Congress on Controversies to Consensus in Diabetes, Obesity and Hypertension (15th – 17th, Bangkok)

JUNE

- Association of Private Hospitals of Malaysia (APHM) Conference and Exhibition (3rd – 5th June, Kuala Lumpur)
- Annual Scientific Meeting of the Malaysian Association of Plastic, Aesthetic & Craniomaxillofacial Surgeons (6th – 8th, Kuala Lumpur)
- The 8th Congress of Asian Society of Cardiovascular Imaging (12th – 14th, Korea)
- 20th ASEAN Federation of Cardiology Congress (13th – 14th, Kuala Lumpur)

JULY

- 2nd Asia Pacific Conference of the International Society of Geriatric Oncology (11th – 12th, Singapore)

AUGUST

- Sarawak Research Day (12th – 13th, Miri)
- Annual Scientific Meeting in Intensive Care (15th – 17th, Kuala Lumpur)
- 30th Annual Congress of the Malaysian Society of Nephrology (20th – 22nd, Kuala Lumpur)
- Annual Scientific Meeting of Malaysian Society of Gastroenterology and Hepatology (22th – 24th, Kuala Lumpur)

SEPTEMBER

- 15th ASEAN Pediatric Federation Congress (17th – 20th, Penang)
- 2nd International Symposium of 'Life Beyond Breast Cancer' (18th – 20th, Kuala Lumpur)
- World Heart Day (29th, Kuala Lumpur)

OCTOBER

- Diabetes Asia 2014 Conference (16th– 19th, Kuala Lumpur)
- The 7th Asia Pacific Heart Rhythm Scientific Session (29th Oct – 1th Nov, New Delhi)

NOVEMBER

- 2014 IASLC Asia Pacific Lung Cancer Conference (6th – 8th, Kuala Lumpur)
- BioMalaysia & Bioeconomy Asia Pacific Conference & Exhibition (19th – 21st, Kuala Lumpur)
- 23rd Malaysian Urological Conference (21th – 23rd, Penang)

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