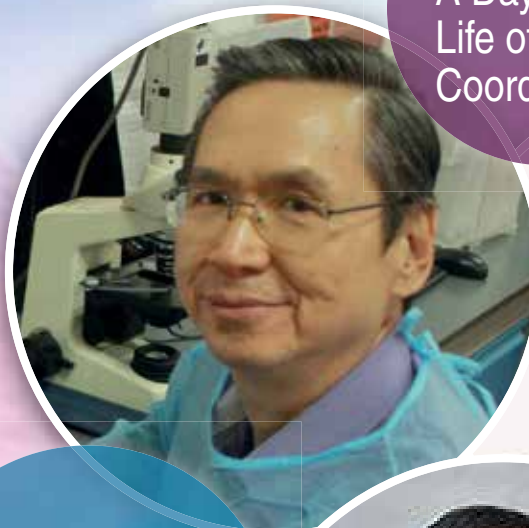


UP CLOSE  
& PERSONAL

A Day in a  
Life of a Study  
Coordinator



KNOWING CLINICAL  
TRIAL 101

Zooming in on  
Homegrown  
CROs



FEATURED SITE

Hospital  
Ampang

RESEARCH  
PERSONALITIES

Prof Dr. Abdul Rashid  
Prof Dato' Dr. Fuad Ismail  
Dr. Lee Han Lim

## COMPLETING THE CLINICAL RESEARCH ECOSYSTEM



## ABOUT CLINICAL RESEARCH MALAYSIA

Clinical Research Malaysia (CRM) is a non-profit company wholly owned by the Government Of Malaysia's Ministry of Health. CRM was established in June 2012 to position Malaysia as a preferred global destination for industry-sponsored research (ISR) and to function as an enabler and facilitator to the industry and medical fraternity.

By working with other stakeholders, CRM strives to improve the local ecosystem to support growth in ISR, facilitate the needs and requirements of industry players, grow the pool of capable investigators, support staff and trial sites, and improve their capabilities and capacities to conduct ISR.

With the Ministry of Health's backing and clear knowledge of the local research environment, CRM is able to provide sponsors (primarily from the pharmaceutical, biotech and medical device industries) and contract research organizations (CRO) with an extensive range of services that includes feasibility studies, investigator selection, placement and development of study coordinators, management of trial budget, review of clinical trial agreements and updates on local laws, guidelines and regulations. CRM also undertakes marketing and promotional activities to build industry awareness about the opportunities for ISR in Malaysia, and create public and patient awareness of clinical trials.



*Your Global Solutions in One Nation*



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## FROM THE CEO'S DESK

Here we are at the end of another fruitful year with various collaborations, meetings and conferences which saw Clinical Research Malaysia's (CRM) network extending beyond the region. I am glad we have accomplished so much. CRM will continue to be committed to provide its services including the feasibility service which will remain as complimentary to sponsors and contract research organization (CROs), hence, bringing more industry sponsored research (ISR) to Malaysia.

This year marked the first ever growth on the number of new clinical investigators since 2008. We have recorded 164 new clinical investigators in 2016 more than doubled the figure in 2015 as recorded in the National Medical Research Registry (NMRR). The number of skilled jobs created in the clinical research industry has grown from 1118 in 2015 to 1491 in 2016 with a 33% growth. CRM has increased its manpower (mainly study coordinators) by 30% to support investigators in the conduct of clinical trials. This, subsequently, creates career opportunities for doctors, nurses, medical assistants and biomedical graduates. The sweetest of all, as of November 2016, 162 new ISRs were recorded versus the target of 155 (4% above target), which means that CRM has already achieved our KPI 1 ahead of time.

In the next 5 years, we will be working towards completing the clinical research ecosystem from the pre-clinical phase of drug development through collaboration with relevant institutions. Thus, this issue of the Bulletin "Completing the Clinical Research Ecosystem" is indeed timely and relevant.

As we mark the end of the year, I would like to thank all members of CRM's Board of Directors chaired by the Hon Datuk Seri Dr. S. Subramaniam, Minister of Health Malaysia, for their support and guidance. We would also like to thank our stakeholders; sponsors, CROs, institutions, investigators, clinical research personnel and all those who have directly or indirectly contributed to the conduct of ISR in Malaysia. Indeed, our achievements today would not have been possible without your hard work and dedication.

We look forward to yet another fulfilling year ahead!

## Enhancing Ties with the Industry

**Putrajaya, Sept 25** – Clinical Research Malaysia organized its second Industry Dialogue on the 25th September. This biannual event serves as a platform for sponsors and contract research organization to collaborate to improve the conduct of clinical research in Malaysia. A total of 60 representatives attended the dialogue session. Speakers from the Royal Customs of Malaysia, Malaysian Bioeconomy Development Corp, Medical Device Authority and Malaysian Investment Development Authority were present to speak on the relevant topics that affects the clinical research industry.



2nd CRM Industry Dialogue 2016

## Bringing Malaysia to Copenhagen

**Copenhagen, Oct 7** – The annual European Society for Medical Oncology (ESMO) congress held from the 7th to the 11th October is a premier scientific platform for researchers, clinicians and industry experts to present oncology research. Clinical Research Malaysia (CRM) led by its Chief Executive Officer, Dr. Akhmal Yusof, and Head of Business Development, Dr. Khairul Faizi Khalid, was at ESMO to showcase what Malaysia can offer to sponsors and contract research organisations and to network with the industry in an to bring in more clinical trials into Malaysia. The congress saw 15,000 participants from 134 countries, 80 exhibitors and 460 invited speakers.

During its presence at ESMO, CRM held meetings with Novo Nordisk and Astra Zeneca at their respective offices to highlight Malaysia's capability and attractiveness in industry sponsored research, in particular for early phase studies. The meetings with the sponsors involved Dr. Akhmal, Dr. Khairul Faizi, clinical trials team from the sponsor companies and the Malaysian Embassy Economic Counselor, Roslina.



Novo Nordisk & Astra Zeneca

## Building Phase I Networks at Hong Kong ICPOEP 2016

**Hong Kong, Nov 3** – Clinical Research Malaysia (CRM) made its presence at the recently concluded 3rd International Conference on Phase 1 and Early Phase Clinical Trials (ICPOEP) held on 3rd – 4th November 2016 at the Hyatt Regency, Tsim Sha Tsui, Hong Kong. This year's conference organized by The University of Hong Kong Clinical Trials Centre (HKU-CTC) attracted over 400 delegates from five continents and 20 countries. This event provided a platform for experts to share the latest trends on early & Phase 1 drug development in various diseases. This was the second time CRM participated in this conference and it has been a good learning opportunity as well as an eye opener to experience how early phase studies are conducted in Hong Kong.



## Making a Presence at DIA Japan After DIA US

**Tokyo, Nov 13** – Clinical Research Malaysia (CRM) represented by Dr. Khairul Faizi, Head of Business Development was at the recently concluded DIA Japan Annual Meeting. The agenda of the conference revolves around the theme 'Breakthrough in Regulatory Science for Patient-Engaged Medical Treatment'. A separate meeting with local Japanese pharmaceutical companies were made to promote CRM's services as well as Malaysia's capability in conducting industry sponsored research. Among the companies that had meetings with Dr. Khairul include Santen, Amato Pharmaceuticals, Toray Pharmaceuticals and Parexel Japan.



NIH Research Week 2016

## National Institute of Health (NIH) Research Week 2016

**Putrajaya, Nov 19** – The 19th NIH Scientific Seminar was recently officiated by the Health Minister, Datuk Seri S Subramaniam in Auditorium Cempaka Sari, Kompleks Perbadanan Putrajaya on the 19th November 2016. Also present were Director General of Health, Datuk Dr Noor Hisham Abdullah and Health Deputy Director General (Research and Technical Support) Datuk Dr Shahnaz Murad. Prof Wienke Boerma from Harvard School of Public Health was also invited as a speaker on behalf of Malaysia's Health System Research (MHSR). The research week resumed at the NIH in Jalan Rumah Sakit, Bangsar, on the 21st – 23rd November with research workshops and plenary talks.

The Research Week 2016, themed "Transforming Health Systems Through Research: Towards Sustainability", brings in Malaysian policymakers, academicians and health system stakeholders to hear experiences shared by international experts on issues related to health system transformation. The objective of the research week is to gather the public health professionals and researchers to present and share the latest findings or health issues through research. It is a platform to impart knowledge as well as to share and identify health based research outcomes and provides up-to-date knowledge on current issues. The event was attended by over 800 participants from various Ministry of Health hospitals and institutions.



## Another Milestone Achieved in P1RP

**Kuala Lumpur, Nov 19** – The third and final workshop for the development of Malaysia's first Phase I Clinical Trial Guideline was successfully conducted last November. The steering committee members were made up of MOH senior investigators, officers from the National Pharmaceutical Regulatory Agency, and experts from contract research organizations. Also present on that day were subject matter experts, Dr. Linda Hakes who is a Pharmaceutical Scientist from the UK and Professor Chim Lang, a Cardiologist from the University of Dundee.

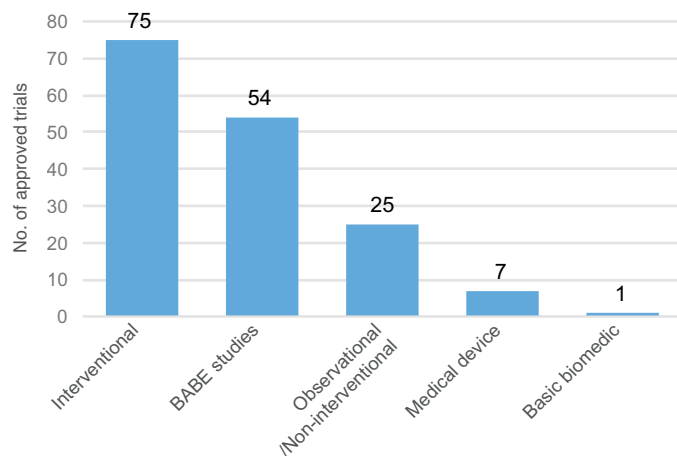
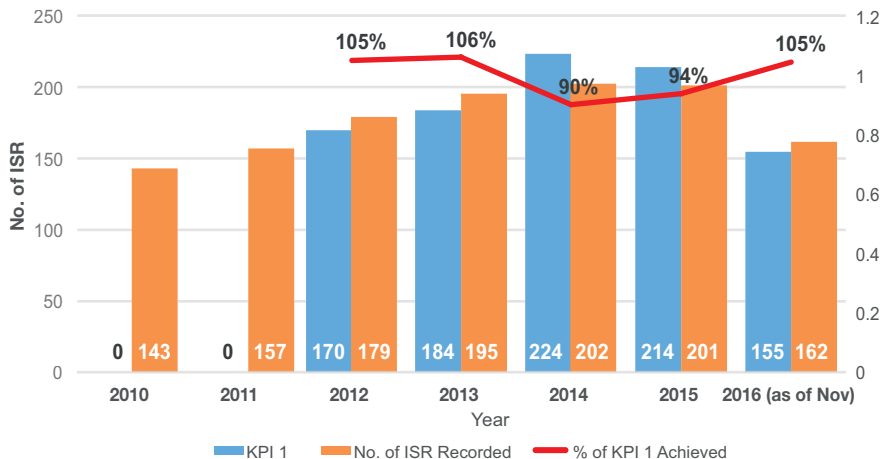
The development of the Phase I Clinical Trial Guideline marks an important step in the Phase I Realization Project (P1RP) blueprint to push Malaysia's involvement in all phases of drug development, in particular, First in Human trials.

## Malaysia's 2016 ISR Statistics

### Number of ISR and Percentage of KPI 1 Achieved

As of November 2016, a total of 162 new industry sponsored research (ISR) was recorded in Malaysia, translating to a 105% achievement of KPI 1. KPI 1 is the number of ISR approved by the Medical Research and Ethics Committee (MREC) and 12 Institutional Review Boards (IRBs) across the country.

*Note: KPI 1 was imposed on CRM upon its inception in 2012.*

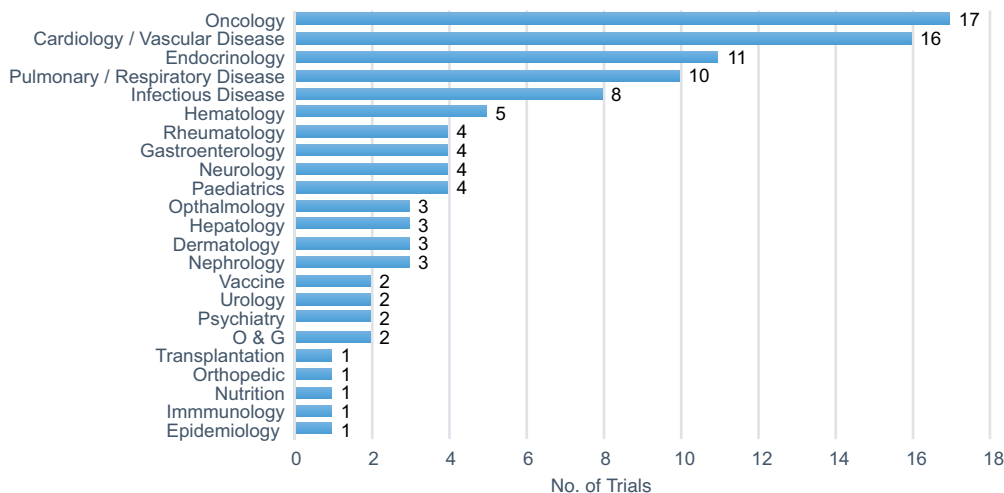


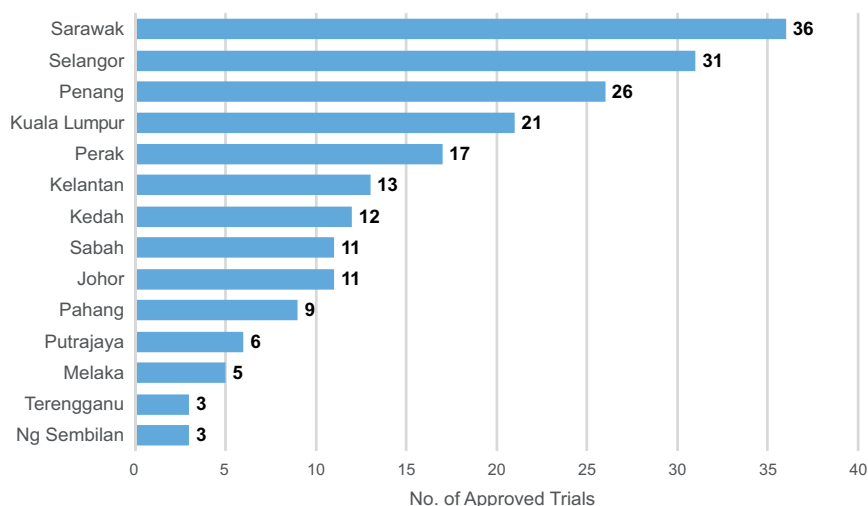
### Classification of Trials from Jan–Nov 2016 (n=162)

Interventional trials comprise the majority of ISRs conducted in 2016, followed by Bioavailability/Bioequivalence (BA/BE) studies and observational/non-interventional studies.

### No. of Trials in 2016 According to Therapeutic Area (Jan–Nov 2016, n=162)

By therapeutic area, oncology trials accounted for the highest number of trials with a total of 17 studies. Endocrinology trials came up close with 16 trials followed by infectious disease and rheumatology trials.



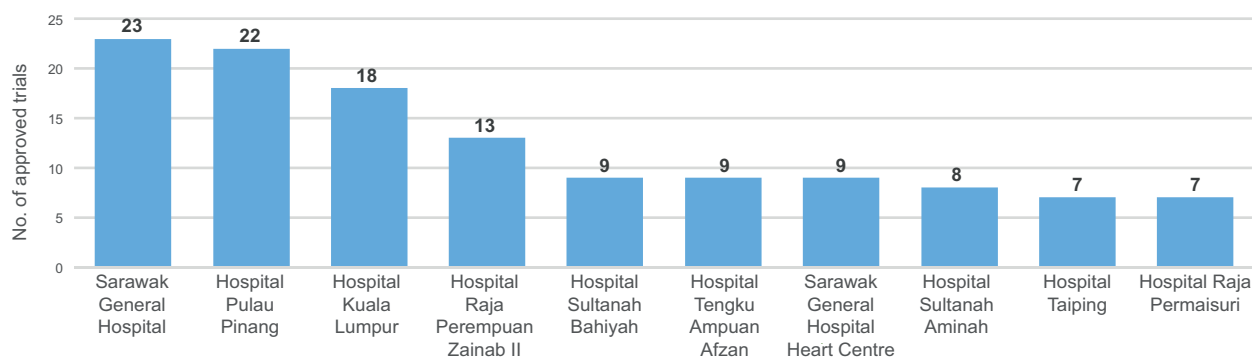


### No. of Approved Trials at MOH Sites According to State (Jan-Nov 2016)

Sarawak recorded the highest number of newly approved trials in 2016 (SGH:23, SGH Heart Centre: 9, H.Sibu: 5, H. Miri: 3). Meanwhile, Kuala Lumpur had 21 approved trials (HKL: 18, IPR: 2, KK Tanglin: 1).

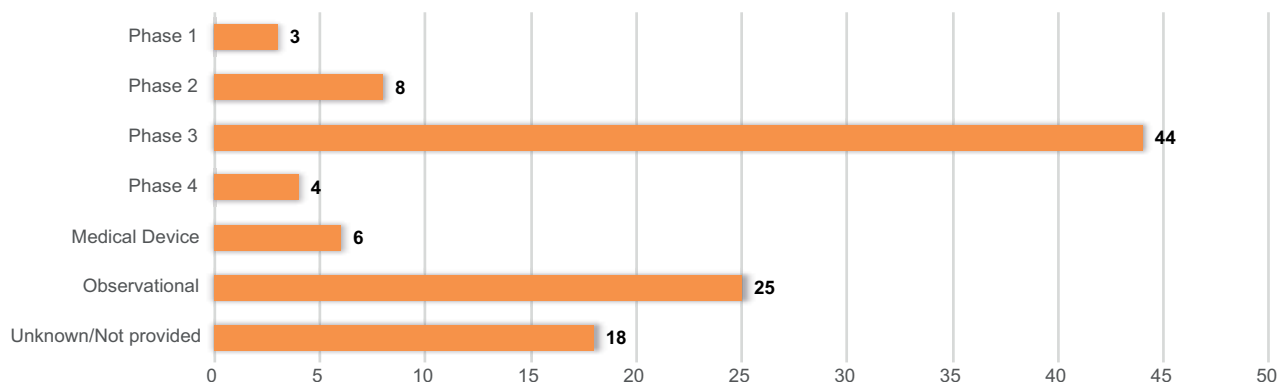
*Note: For multicenter trials, the same trial can be conducted at different sites with different principal investigators.*

### Top 10 MOH Sites with the Most ISR Trials in 2016 (Jan-Nov)

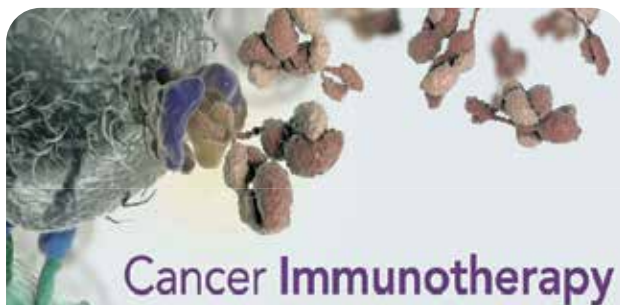


*Note: For multicenter trials, the same trial can be conducted at different sites with different principal investigators.*

### Number of Trials Approved in 2016 According to Phases



*Note: BABE studies are not included as it is not a trial phase.*



## Immune therapy for brain tumors:

A new promising avenue Glioblastoma is a particularly aggressive type of brain cancer. Only about one fifth of adults diagnosed with it survive two years or more after their diagnosis. A new two-drug combination, currently in early clinical trials, might help people diagnosed with glioblastoma to fight the disease. In a presentation of early clinical trial data to the 20th Annual Scientific Meeting of the Society for Neuro-Oncology, physician scientists from the University of New Mexico Comprehensive Cancer Center reported that a large number of study participants responded well to the drug combination.

*Source: University of New Mexico Comprehensive Cancer Center (February 3, 2016)*



## Ebola vaccine: Promising phase I trials

"The results for tolerability, safety, and the immune response to the vaccine candidate are very promising," explains Prof Marylyn Addo. The antibodies which developed against the virus were still detectable after six months. Addo is convinced, "With this, a single vaccine could provide lasting protection against Ebola." The infectious disease specialist, who works for the German Center for Infection Research at the University Medical Center Hamburg Eppendorf (UKE) in Hamburg, led the trial in Hamburg. A total of 158 healthy adult volunteers were tested in Hamburg, as well as at the partner sites in Geneva (Switzerland), Lambaréné; (Gabon) and Kilifi (Kenya).

The scientists involved are participants in VEBCON, a consortium of experts founded by the WHO, the goal of which is rapid and coordinated clinical testing of the Ebola vaccine in Africa. A vaccine is still urgently needed, since the current Ebola epidemic has not yet been completely defeated and future outbreaks cannot be ruled out.

*Source: German Center for Infection Research (May 3, 2016)*



## Expectations may not match reality among cancer patients in some early phase clinical trials

In a study of cancer patients considering whether they should participate in phase I clinical trials, a high percentage were willing to participate after discussions with clinical staff, but nearly half thought that their tumors would shrink, which is much higher than what is realistically achieved. Published early online in *CANCER*, a peer-reviewed journal of the American Cancer Society, the findings demonstrate the challenges facing patients and healthcare professionals during their interactions in phase I studies.

Phase I trials are designed to assess the potential of investigational treatments that have never before been tested in humans. The trials, which are often restricted to patients with advanced disease that has not responded to standard therapy, start with conservatively low doses of a drug or other therapy and escalate until a recommended dose for a phase II trial is established. Typical response rates of phase I cancer trials range from four percent to 20 percent, and enrolled patients survive for a median of six months.

*Source: Cancer (September 26, 2016)*







## High response rate in phase I/II pediatric brain cancer trial sets stage for combination therapy with higher response, lower toxicity

A high response rate with a single drug in a phase I/II trial of paediatric brain tumour has set the stage for combination therapy with higher response and lower toxicity, researchers reported at the ESMO 2016 Congress in Copenhagen.

"The likelihood of curing a child with a low-grade glioma is very high," said lead author Dr Mark Kieran, Director, Paediatric Medical Neuro-Oncology, Dana-Farber Boston Children's, Boston, US. "In fact many children don't suffer lifelong from the tumour but rather from the cognitive damage and secondary malignancies caused by radiation therapy." He continued: "The development of drugs that target the specific causative mutation of the tumour and avoid long-term toxicities may revolutionise the treatment of paediatric brain cancer."

*Source: European Society for Medical Oncology (ESMO) (October 7, 2016)*



## Phase I study of novel anti-cancer drug uses tumour mRNA expression to identify responders

The first-in-human dose escalation study of the pan-FGFR (fibroblast growth factor receptor) inhibitor BAY 1163877 in patients with treatment-refractory locally advanced or metastatic solid tumours were reported today at the ESMO 2016 Congress in Copenhagen. The novel compound uses messenger RNA (mRNA) in tumours to identify patients who will respond.

"Most studies of FGFR inhibitors have looked at FGFR abnormalities in tumours with limited success," said lead author Dr Markus Joerger, attending medical oncologist, St Gallen Cancer Centre, Switzerland. "This study used an innovative biomarker approach of tumour FGFR mRNA expression." This multicentre phase I study was conducted in six countries. The dose-escalation study was followed by expansion cohorts in patients with high tumour FGFR mRNA levels. A total of 80 patients were enrolled and treated, including 23 patients in the dose-escalation phase and 57 patients in the expansion cohorts in bladder cancer, head and neck cancer, lung cancer, and all comers.

*Source: European Society for Medical Oncology (ESMO) (October 8, 2016)*



## Phase I trial shows that a drug that inhibits the Notch signalling process is active in a range of advanced cancers

A new anti-cancer drug that inhibits a key cell signalling process involved in many different cancers has shown that it is capable of stopping the progression of cancer and shrinking tumours. Importantly, it has been able to do this in rare cancers that are less well-studied such as adenoid cystic carcinoma.

Dr Christophe Massard, a senior medical oncology consultant and chair of the Early Drug Development programme at the Institut Gustave Roussy Cancer Campus (Villejuif, France) told the 28th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in Munich, Germany, that results from a phase I clinical trial in 103 patients showed that the drug LY3039478 was successful in inhibiting the Notch signalling pathway in patients with alterations in the Notch protein.

Patients in the trial had a range of cancers, including breast, colon, parotid (salivary gland) and sarcoma, which were all advanced or had started to spread to other parts of the body (metastasise). After treatment with LY3039478, the tumour shrank in one patient with breast cancer and the disease stabilised and did not progress in another 29 patients. In addition, using PET scanning, researchers found two more cases where the tumours had shrunk: in a patient with adenoid cystic carcinoma and a patient with testicular cancer.

*Source: The European Cancer Organisation (ECCO) (December 1, 2016)*

# On pre-clinical research DR. LEE HAN LIM



Dr. Lee Han Lim first started as a Medical Entomologist (Research Officer) in the Unit of Medical Entomology, Institute for Medical Research (IMR) in 1978 before being appointed Head of the Unit in 1993 and Head of WHO Collaborating Centre for Vectors. He obtained a Masters of Science (Medical Entomology) from Universiti Sains Malaysia before graduating with a PhD in this field. Dr. Lee is also a former Dean of School of Diploma in Applied Parasitology & Entomology from 2004 to 2011. He retired in 2011 and was re-employed under contract between 2011 and 2016.

His main research is in vector biology and control, with a research interest in Dengue, Zika and Chikungunya vectors, re-emerging and exotic vectors, microbial control agents, insecticide resistance, forensic entomology, maggot debridement therapy, transgenic mosquito, Wolbachia and sterile insect technique. He has a list of major achievements during his tenure at IMR with a long list of "Firsts" in research accomplishments. To date, he has a total of 315 scientific publications, 159 theses/reports/proceedings/guidelines, 512 paper presentations in seminars, 64 major research grants, 19 patents filed/granted and 9 commercialised/pre-commercialised products.

## ***What are the important roles played by the Entomology Unit at IMR and what is its research focused on?***

The Medical Entomology Unit was established in 1902 with the appointment of the first entomologist at the Institute for Medical Research. Various researches on insect-borne diseases have been carried out here for more than 11 decades on vector biology and control of insects and their relationship to diseases. Many of the techniques of control and suppression of disease-bearing insects used in today's modern era, originated from this Unit. Medical Entomology Unit plays four important roles: Research, Training, Diagnosis and Advisory / Consultancy. Since 1985 and to date, the Unit is designated as the WHO Collaborating Centre for Ecology, Taxonomy & Control of Vectors of Malaria, Filariasis and Dengue.

## ***How has the research environment/ecosystem evolved from the time you joined IMR up until your retirement?***

When I first joined the Unit in 1978, the research scenario was in a state of transition. Malaria and filariasis were no more major public health issues and in the process of being eradicated, while dengue had gradually spread nationwide and the scale of dengue outbreaks were slowly but surely gaining public health significance. During these ensuing years, advances in biotechnology, especially molecular biology were explosive and their application in biomedical sciences, such as research in vectors, was rapid and

gaining speed. In addition, during this period, we also saw the Government's new policies in R&D, which came with many folds of increase in funding and expansion of research scopes in many areas, inclusive of biomedical fields. It was a golden era for researchers, really, because our only limitations were to generate innovative ideas!

## ***Can you describe two research projects which you were involved in and its impact in the medical field.***

I have been the Principal Investigator in more than 100 research projects. Below are two examples of important past research:

- (i) Maggot Debridement Therapy (MDT) – using sterile (microbial free) fly maggots to debride (clean) wounds is not new and used since time immemorial. It is an accepted clinical practice in modern medicine, especially since the emergence of antibiotic resistance. In the West, the temperate fly *Lucilia sericata* is used, but in the tropics, like in Malaysia, only another species, *Lucilia cuprina* is present, but no study was ever conducted to test its possible use in MDT. We therefore developed maggot sterilizing techniques, and conducted clinical trials which proved this species was as effective as the temperate species. Subsequently MDT is now introduced and used in 52 hospitals in Malaysia, mainly to debride diabetic wounds. So far, we have treated more than 4000 patients, mostly diabetics and in many cases limb amputation is avoided.
- (ii) Forensic Entomology Research – This involved the use of maggots from corpse to determine the post-mortem interval (time of dead), cause of death and place of death. Such evidence is accepted by court of law. We conducted large scale study using monkey carcasses in all known ecotypes in Malaysia and collected & identified many types of forensic flies. These voluminous data are widely used in forensic cases. So far, we have provided assistance to police investigation in more than 700 cases and identified thousands of forensic flies.

## ***In your opinion, why is it important for IMR to work collaboratively with the MOH and universities?***

While collaboration in research has been an integral part of research, in the past, the nature of collaboration was conducted within departments/disciplines/institution. However, increasing complexity in research questions necessitates partnership across departments/disciplines/institution (e.g. university, ministry). Such form of collaboration is more likely to generate innovative ideas and breakthroughs, and solutions to new, complex and convoluted fields of research. Collaboration is beneficial to participating parties, in term of funding, expanded capability, division of labour, sharing of resources and technological advances, intellectual property and publications.

## ***In the field of research, where do you wish to see Malaysia in the next 10 years?***

The present policies in science and trend of research will shape the future position of Malaysian in scientific research in the decade to come. Presently, we are still a nation more on acquiring and using technologies researched and developed by others, and less on generating new knowledge and groundbreaking technologies. If we were to be on par with the technologically advanced nations of the world in future, it is pertinent to invest heavily in basic and fundamental research, as well as translational research.

Professor Dr. Abdul Rashid is one of the pioneering Clinician Scientist in Malaysia. He was trained in both Internal Medicine and Clinical Pharmacology in the United Kingdom. He pioneered the establishment of the Clinical Trial Unit at USM Kota Bharu, the Advance Medical and Dental Institute at USM Penang and the Clinical Trial Center in Cyberjaya University College of Medical Sciences. He is also a pioneering member of the National Committee of Clinical Research and the Chairman of the Malaysian GCP Guideline. Prof Rashid is currently Medical Director and Consultant Physician at An Nur Specialist Hospital, Visiting Professor to a few universities and a Visiting Consultant for clinical research at the National Heart Institute.

Prof Rashid, as an experienced clinician scientist in early phase clinical trials, how important is early phase studies to the medical world?

It is crucial! Ibn Sina (Avicenna) more than a millennium ago outlined 7 principles to determine whether a treatment works. One of the principles is that if it works in animals, it does not necessarily mean it works in human. Ibn Sina is the true father of Modern Medicine and Evidence Based Medicine!

#### ***How do you think Malaysia can benefit from conducting early phase studies?***

When we started in the late 80s and early 90s, we were only doing 'clinical trials' on marketed drugs because the industry wants our doctors to get use to the drugs and then use it in our daily practice. In the late 90s onwards especially when we launched our GCP Guideline (1999) and then made it compulsory for clinical researchers (early 2000s), phase 2 and 3 trials came flooding to our shores. I clearly remembered giving a talk on Malaysia's 10 years' experience on GCP Training and was informed by a representative from a multinational company that Malaysia is not ready for Phase 1 trial yet. This was in October 2008. I felt at that time that we as a nation were being challenged! If and when we are acknowledged to be capable of conducting Phase 1 trials, it will be a testimony that we have made it in terms of completing the ecosystem for clinical trials. To me personally we should not be contented to perform contract research even at Phase 1 level. Our involvement in Phase 1 contract research should be a fore runner for our own initiative to discover new drugs. We have a sizeable number of scientists doing basic drug research on animals. We have clinical trialists with vast experience in phase 2 and 3 trials. Developing capacity for phase 1/First in Man trial will be icing on the cake.

**I dream of a discovered-in-Malaysia product which has been researched in Malaysia from pre-clinical right through to phase 3 trials.**



On early phase clinical trial

**PROF  
DR.  
ABDUL  
RASHID**

*Medical Director and Senior Consultant  
Physician, An Nur Specialist Hospital*

#### ***Do you think that Malaysia is ready to embark on conducting early phase studies (ie. First in Man) and why?***

Not yet but we are taking the right steps. To me the critical success factor will be the 'software' not the 'hardware'. By that I mean the human capital. We need to bridge the gap between the current expertise we have in animal research and middle (Phase 2 and 3) to late (Phase 4) phase clinical trials. We need to have a critical mass of clinical pharmacologists, clinical toxicologists, clinical trial methodologists and translational researchers.

#### ***In your opinion, why is it important for the Ministry of Health, institutions and the universities to work collaboratively towards developing a complete ecosystem in clinical research?***

I see this already happening partly by design. I was personally involved as Chairman of the Health Cluster for the now defunct Intensification of Research in Priority Area (IRPA) where we insisted that researchers must show evidence of collaboration with other researchers especially when they apply for big grants in the Prioritised Research category. Malaysia is a small nation with an even smaller researcher community especially in clinical research. It is thus crucial that clinical researchers collaborate to avoid missed opportunities and unnecessary duplications in redundancies. When it comes to health research, the MOH, being the ultimate guardian and biggest stake holder must obviously take the lead so that research done will be focused to the national health agenda and needs.

#### ***In the field of clinical research, where do you wish to see Malaysia in the next 10 years?***

For clinical research as a whole, I dream of a major trial initiated and conducted in Malaysia which will change clinical practice and quoted in Clinical Practice Guidelines, not just locally but internationally. Thailand and Vietnam have done it. Why can't we? To do that we have to be focused and galvanise our expertise collectively. For drug development, I dream of a discovered-in-Malaysia product which has been researched in Malaysia from pre-clinical right through to phase 3 trials. Hopeful it becomes a best seller too! Expertise in Phase 1 trial is currently among our weakest links. That needs to be addressed sooner rather than later.



# On late phase clinical trials PROF DATO' DR. FUAD ISMAIL

Clinical Associate Professor, Department of Radiology, Faculty of Medicine,  
Universiti Kebangsaan Malaysia (UKM)



Professor Dato' Dr. Fuad Ismail graduated from University Kebangsaan Malaysia (UKM) with a MD in the year 1990. He obtained dual Fellowships from the Royal College of Surgeons Ireland and Royal College of Radiologists London in 1996. Prof Fuad currently serves at UKM as a Clinical Associate Professor of Oncology. He supervises and serves as an examiner for postgraduate Oncology students in addition to his regular clinical duties. He is also currently the Head of Department at UKM Oncology & Radiotherapy Department since 1999 and Chairman of the Ethics Committee in UKM since 2010. Prof Fuad has contributed as a Committee Member to various Clinical Practice Guidelines for cancer treatment, and most recently in the Management of Cervical Cancer (2015). He is a Committee Member of the Malaysian Oncological Society (MOS) and has authored 26 publications in peer-reviewed journals. Prof Fuad speaks regularly at scientific symposia and has served as a Faculty Member at more than 114 regional and national conferences. He is also actively involved in community service.

***Prof Fuad, you have been involved in many oncology clinical trials at UKM. In your opinion, how can phase 2 and 3 clinical trials help broaden treatment options for doctors and patients in this field?***

Many oncologists actually participate in clinical trials to give their patients an additional option for therapy. There is the altruistic motive of developing and improving drug therapy but a big portion is also in expanding drug access through a clinical trial. Therapies considered "standard" in Europe and the US, for example Herceptin, as adjuvant for breast cancer, is not readily available here for our patients due to its cost, but by enrolling them into clinical trials, whether in the metastatic or adjuvant setting, allows them to have access to these standard therapies. These are particularly for Phase 3 trials as it is usually a new drug versus standard therapy. For phase 2 trials the motivation is more towards development of new products (drugs).

***Why do you think it is important for the Ministry of Health, institutions and universities to work collaboratively towards developing a complete ecosystem in clinical research?***

We need to build capacity to be able to develop our own drugs. This is very ambitious given the complexity of the process and the enormous funding required but we do want to move up the value ladder. It is easier to do later phase trials compared to a Phase 1/2 trial but these are the trials that are at the head of innovation, and eventually we should try to move towards researching and trialing our own products. Having said that, product development would more likely be in collaboration with a major pharmaceutical as partner, if at all possible.

We need to build capacity to be able to develop our own drugs. This is very ambitious given the complexity of the process and the enormous funding required but we do want to move up the value ladder.

***In the field of clinical research, where do you wish to see Malaysia in the next 10 years?***

I hope we would be able to catch up a bit with Singapore who are now testing out their own products and innovative therapies. We should be doing Phase 1/2 trials routinely and be one of the preferred partners. We would need much more coordination and reduce duplication of work/equipment. To do this, the remuneration must be more attractive as to reduce the need for specialists to conduct many clinics and the senior ones would be able to give directions rather than work as foot soldiers.

***How has CRM made a difference in the clinical research ecosystem in Malaysia?***

CRM has done a good job coordinating some of the research and taking some burden away from researchers, for example providing Study Coordinators. I would like to see CRM being more coordinated with the various centres (eg. with trial updates, new potential projects etc.). At present I think we are still working in silos and know little about what happens outside our institutions and are only updated in person when we meet at meetings. Perhaps some brainstorming session between different institutions would help and guide people to specialize in certain areas rather than to be in competition. CRM can structure to knit MOH, MOHE and different organizations (eg. CARIF) as long as they remain neutral and not strongly affiliated with a particular Ministry.



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The CRM Bulletin is published three times a year with a print run of 3000 copies per issue. These are delivered complimentary to a local and foreign readership base comprising of: Doctors and investigators (public and private); Hospitals (public and private); Sponsors and CROs; Universities and academics involved in clinical research; Medical research centres; Senior government and MOH officials; Clinical Research Centre (CRC) staff and investigators; Ethics Committees, Patient support groups; and selected medical schools.

The print run is complemented by an online subscriber base of 2000 readers currently, who receive an online copy of the CRM Bulletin.

The bulletin's objectives are to spread awareness about Malaysia's capabilities in industry sponsored clinical research (ISR), inform and attract industry players to Malaysia, motivate and educate potential investigators and support staff, build public awareness about the importance of clinical research, and finally serve as a forum to share news and development relevant to all stakeholders.



### OTHER PUBLICATIONS BY CRM



Guide to BA/  
BE Centres  
in Malaysia



Malaysian Guide on the use of  
Human Biological Samples  
for Research



NCCR bulletin



Guide for Industry



Patient Brochure



## A Day in the Life Of A Study Coordinator

By Matron Lim Chooi Eng, CRM,  
Hospital Pulau Pinang (HPP)

I have always thought being a study coordinator is nothing short of the ordinary. I had done many research papers and had also been involved in many investigator initiated research papers during my nursing days and I was very confident of myself. I was so confident of myself that I included all the abstracts of the studies that I had previously done in my folio when I went for the interview with Matron Wakia at CRM office.

The first day I reported to work at CRC Penang Hospital, I walked in with an air of superiority, thinking I know how things work and it will be a breeze working as a study coordinator. But the bubble that was my ego was soon to burst. Nothing in all my 38 years of nursing could prepare me for this line of work. I discovered it is so completely different and I had to learn the ropes of a study coordinator right from scratch.

I am the proverbial dinosaur in information technology and having to perform everything online was to be the bane of all my hardships. I struggled even to key in the password to log in online. I had to enlist the help of my colleagues every time there is new access to obtain. Imagine how much patience my colleagues had to endure to put up with my foibles. I remembered once after I had obtained access to one study IWRS portal, I thought to try out the portal to familiarize myself with it. I was unaware that the moment I clicked on the 'submit' icon, I had inadvertently enrolled a patient into the study when there was none. There was so much anxiety thereafter as we had to enlist the Global Helpdesk to cancel the enrolment in time for the next incoming subject to be enrolled.

Information Technology was indeed tough for me and I almost wanted to throw in the towel. However, I checked myself in time. I am not one to admit defeat easily. My tenacity and perseverance paid off and soon I was getting more adept at the computer. Of course I have my colleagues to thank for too.

The activities following a patient visit can also be very daunting to someone new to this line of work. It was particularly challenging having to remember so many protocols and to identify them to that particular study. The corresponding laboratories and the different courier services contracted for each study added to the confusion. Nevertheless, I continued to observe and "hands-on" under the supervision of my "seniors".

The day I can say I truly "graduated" was the day I was entrusted to "hold the fort" when my "seniors" had other engagements out of Penang.

Handling feasibilities, on the other hand, is my forte as I am familiar with most Principal Investigators and their specialities.





For the first few months I concentrated on getting as many feasibilities as possible to the Principal Investigators (PIs) before the targeted datelines. We are seeing more PIs showing interest in studies and it is always a plus point for us when we get a new PI answer feasibility with a favourable response. Nothing beats the feeling of exhilaration every time a PI show interest in a particular study. It is akin to baiting a fish on the fishing rod and every time it is like, "Yay, we got another feasibility answered". We can also imagine the excitement of the feasibility specialists down at AMCORP Mall whose constant encouragement give us an added impetus to continue with our efforts.

In CRM Penang, we are truly ONE MALAYSIA. We have every race represented here and we work together as a team. We complement each other very well. The expertise I have in the medical and nursing field, I impart to them. On the other hand, their IT prowess more than make up for my lack. My IT knowledge improved tremendously due to their diligent coaching.

I may be forgetful at times, but I am thankful that the young people in my team will often give me reminders. They are also my hands and my feet. IN HPP, space is a very precious commodity. We are always vying for space to store our ISF, laboratory kits and specimen boxes. Very often we had to ask

sponsors to purchase cabinets for the storage of these items. Having procured them there is the added dilemma of where to place them. We are very adept now at identifying nooks and corners to site the cabinets.

Every single space is precious and cabinet tops are also stacked to the brim with boxes. My colleagues are most ready to climb up ladders to reach the uppermost recesses of the cabinet where my creaky bones do not permit. Having to reach down for items stored at the lowest shelf of the cabinets can be a back breaking exercise but they will do it happily for me to spare my suffering knees from injury. I am very thankful to all of them for their willingness to do that extra bit for me.

How does one gauge whether one enjoy working in a particular workplace? I am reminded of this comparison. If one jumps out of bed with a renewed exuberance every morning expecting a great day ahead of oneself no matter how busy the day may be, then one can truly say that workplace is "heaven on earth". However, if one have to drag oneself from one's bed dreading what is ahead for the day, then one is experiencing "hell on earth".

Well, I can say that I belong to the first category and I feel great belonging to TEAM CRM.



## CRM INDUSTRY SPONSORED RESEARCH AWARD 2016

During the last CRM Industry Dialogue held on 25th October 2016, several awards were given out to clinical trial sites and principal investigator (PI) to acknowledge their unwavering commitment and effort in the conduct of industry sponsored research, and to spur and encourage such efforts in the future. CRM would like to congratulate the below sites and PI for their achievements.



### DR GOKULA KUMAR A/L APPALANAIDU

Institut Perubatan & Pergigian Termaju ( IPPT ) - USM

Highest Number Of Positive  
Responses Towards  
Feasibility Studies in 2015



### HOSPITAL SERI MANJUNG

The Second Highest Recruiter In  
Asia-Pacific Region For The  
Vision Study



### HOSPITAL PUTRAJAYA

The Highest Recorded Count For  
The Newly Approved Endocrinol-  
ogy Clinical Trials In Year  
2015



### KLINIK KESIHATAN GREENTOWN

The Highest Number Of Industry  
Sponsored Research Among  
Primary Health Clinics In  
Malaysia From 2011–2016



### HOSPITAL KUALA LUMPUR

The Highest Recorded Count For  
The Newly Approved Oncology  
Clinical Trials In Year 2015



### SARAWAK GENERAL HOSPITAL

The Highest Recorded  
Count For The Newly Approved Cardiology  
Clinical Trials In Year 2015







# Hospital Ampang

## Clinical Research Ward

Clinical Research Ward (CRW), Hospital Ampang was established in 2010 as a collaborative unit between a global contract research organization, named Veeda Clinical Research and the National Clinical Research Centre (NCRC), Ministry of Health. To embrace the collaboration, the facility was initially named as CRC-Veeda-Malaysia (CVM). The primary objective of the collaboration was to spearhead the development of early phase clinical research in Malaysia and to prepare a local team for conducting early phase clinical studies. More importantly, the collaboration provides a gateway to bring forward our local drug development from non-human phase to early phase clinical research.

Moving forward, CRW is now a fully established research facility under the governance of Clinical Trial Unit (CTU) of NCRC. The research facility is now operated by a research team of medical officers, pharmacists, nurses and science officers. The CRW team has completed more than 15 bioequivalence studies, one intensive pharmacokinetic investigation for a DNDi<sup>1</sup> study in hepatitis C and one multicenter retrospective study in anemia aplastic till 2016. Besides, the CRW team is also supporting the conduct of many investigator initiated researches (IIR) by offering expertise and consultation in study design, statistical analysis, data management, study drug management and project management.

<sup>1</sup> Drugs for Neglected Diseases Initiative (DNDi)



## FEATURED SITE

Research operations at CRW are governed by over 100 different standard operating standards (SOPs), covering areas such as project management, clinical operation, subject recruitment, pharmacy, quality assurance, quality control and so on.

The SOPs are improvised based on current operational needs and standards from time to time, to ensure sustainability in operational quality.



### Facilities at Clinical Site

- 46 research beds
- Cardiac monitors
- Ultralow freezers
- 2 screening rooms
- Documentation room
- Pharmacy room
- Sample processing room
- Recreational room
- GPS-synchronized clocks
- Internet access for patients
- CCTV

Essential equipment and rooms are monitored through a third party monitoring system, which helps notify the investigators of unexpected temperature and humidity excursions.

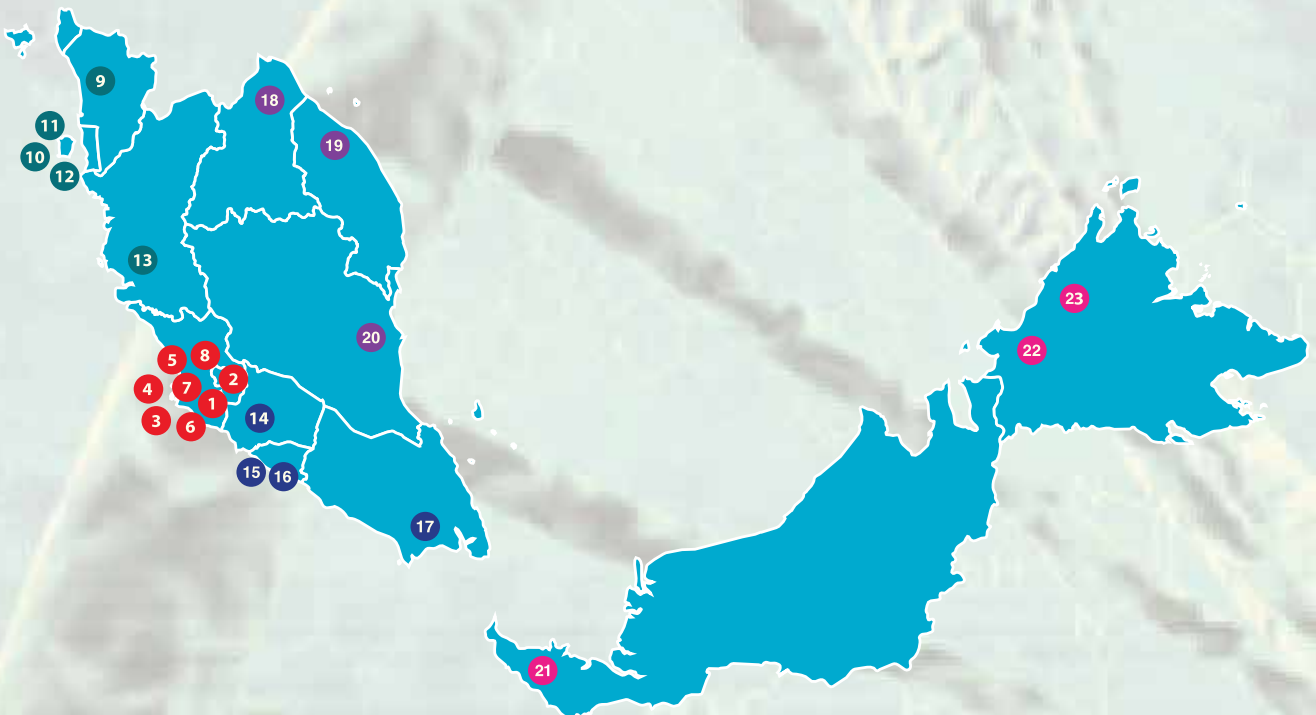
The CRW is one out of 10 Bioavailability/Bioequivalence (BA/BE) sites (with an external bioanalytical site) which has been accredited by the National Pharmaceutical Regulatory Authority as being a BA/BE compliance site.



The creation of CRW as a platform to conduct early phase clinical studies is in line with the vision and mission of NCRC to become a leading clinical research organization in Asia, to improve patients' health outcomes through ethical and quality clinical research and to attract biotechnology companies and contract research organizations to conduct clinical research in Malaysia. Therefore, CRW strives to support NCRC and the nation by continuously expanding its capacity and expertise in early phase clinical research.

# Active Sites Performing Oncology Clinical Trial

- 1 Kuala Lumpur Hospital
- 2 National Cancer Institute
- 3 Ampang Hospital
- 4 Subang Jaya Medical Centre
- 5 Pantai Medical Centre, KL
- 6 UMMC - University Malaya Medical Centre
- 7 Beacon International Specialist Centre
- 8 Universiti Kebangsaan Malaysia Medical Centre
- 9 Sultanah Bahiyah Hospital
- 10 Penang General Hospital
- 11 Gleneagles Medical Centre Penang
- 12 Mount Miriam Cancer Hospital
- 13 Raja Permaisuri Bainun Hospital
- 14 Nilai Medical Centre
- 15 Melaka Hospital
- 16 Mahkota Medical Centre
- 17 Sultanah Aminah Hospital
- 18 Raja Perempuan Zainab II Hospital
- 19 Sultanah Nur Zahirah Hospital
- 20 Tengku Ampuan Afzan Hospital
- 21 Sarawak General Hospital
- 22 Queen Elizabeth Hospital
- 23 Sabah Women and Children's Hospital





## Active Sites Performing Cardiology Clinical Trial

- 1 Serdang General Hospital
- 2 Sarawak General Hospital
- 3 Queen Elizabeth II Hospital
- 4 IJN - National Heart Institute
- 5 Raja Perempuan Zainab II Hospital
- 6 Sultanah Bahiyah Hospital
- 7 Penang General Hospital
- 8 Tengku Ampuan Afzan Hospital
- 9 Sultanah Nur Zahirah Hospital
- 10 Sultanah Aminah Hospital
- 11 HUSM - University Science Malaysia Hospital
- 12 HUKM - University Kebangsaan Malaysia Hospital
- 13 UMMC - University Malaya Medical Centre
- 14 UITM - University of Technology Mara





# ZOOMING IN ON HOMEGROWN CROs

This section on Malaysian contract research organizations (CROs) provides a glimpse on several homegrown CROs who have made a name for themselves in the clinical research industry.



## Info Kinetics

### Connecting Research & People

Research matters most when it adds value to the people's health outcomes. As a home grown Clinical Research Organisation (CRO), Info Kinetics pioneered the ASEAN's first accredited commercial Clinical Research and Drug Analysis facility. Info Kinetics' accreditations and inspections (EMA & US FDA) had enabled their clients to gain worldwide market authorizations. Info Kinetics is repeatedly engaged by clients to add value to their clinical development programme.

With a hospital based Clinical Pharmacology Unit and a track record of over 420 early phase studies (e.g. bioequivalence, relative bioavailability, 505(b)(2), Article 10(3) Hybrids, Phase I studies), Info Kinetics aims to set the benchmark for quality standards in early phase and drug analyses in the ASEAN region. Info Kinetics has an added advantage over other competitors with its strong alliance

and collaborations with governmental agencies, various global CROs, which provides business referrals and marketing of its services through its international network.

Info Kinetics' clientele which include generic drugs companies, CROs, research institutes and academic institutions had often regarded Info Kinetics as a platform of possibilities. In short, our competitive edge is our cost-effectiveness in providing clinical trial solutions to this region and benchmarking the highest standards of quality.

### Key Personnel

Info Kinetics' core scientific team consists of Pharmacokineticist, Clinical Pharmacologist, Interventional Cardiologist, Molecular Biologist, Oncologist, Diabetologist and Immunologist with extensive experience in translational research. They are assisted by a research team of physicians, pharmacists, clinical research associates, nurses, chemists and administrators.



### Contact

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## 'The Outstanding Partner in ASEAN for Drug Development'

Borneo Kinetics Sdn Bhd is the first Sarawak-based "Contract Research Organization (CRO)" providing drug development services to both ASEAN and international pharmaceuticals and consumer healthcare industries. We are approved to be in the list of BE Compliance Program by National Pharmaceutical Regulatory Agency (NPRA). All clinical trials are conducted in compliance with the Good Clinical Practice (GCP) to ensure the quality of the trials especially the rights, safety and well-being of subjects, and clinical data credibility.

### Collaborative Partners

We maintain long term partnership with local research centers, among them are:

**Clinical Research Centre (CRC) Kuching** – 3rd CRC established by Ministry of Health Malaysia, which foster the research needs across the clinical disciplines, ranging from early phase to Phase IV clinical trials, as well as the investigator-initiated research activities (pharmacogenetics, pharmacoconomics & epidemiology).

**Info Kinetics Sdn Bhd** - a ISO17025 Certified since 2003, OECD GLP compliance and inspected by French Regulatory Authorities (2008), Malaysian Regulatory Authorities (2003) and U.S. Food and Drug Administration (2013); has been our long-run partner in bioanalytical services since we established in 2012.

### People Passionate in Delivering Value

We have a dynamic team which comprises of GCP-trained research physicians, nurses, clinical pharmacists, study coordinators and quality assurances.

### Our Services

Together with our partners, we offer in vitro dissolution testing, study design/protocol development, regulatory/EC submission, project management, data/pharmacokinetic analysis and development of bioanalytical/clinical study report.

### Our Clinical Ward

- A dedicated 26-bedded ward with CCU facilities and cardiologists stand by
- A controlled access sample processing room with refrigerated centrifuge and deep freezers
- A temperature- controlled drug storage area and archive room with limited access.

### Contact

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Tel: +6082668111 (Ext 8075)

E-Mail: borneokinetics@gmail.com

Website: borneokinetics.blogspot.com

Facebook: BKvolunteers Club





MyXMO started as MySMO, the operations arm of the Clinical Research Centre, Government of Malaysia in 2008 and became a full fledged clinical research organization (CRO) in 2010. In 2014 MySMO ceased operations and MyXMO was born taking over its full scale of operations under the able capabilities of the same CEO.

Being a pioneer in the clinical trial scene and with many envious projects in its past, MyXMO has the entire gamut of services to take your study to successful completion. We provide Comprehensive, Cost Effective, Tailor-made packages and services to meet your expectations with Great Quality and under the regulatory framework of clinical research.

With excellent networking opportunities in the local clinical trial community and a history of global partnerships MyXMO is well placed to take the Malaysian government's push to promote Malaysia as a regional clinical trial hub forward. Our past clients include pharma majors to CROs and independent clinical investigators.

MyXMO has a vibrant team coupled with a 20 years seasoned CEO to offer clinical trial management services that focuses on a wide range of clinical trials. We offer a one stop shop for all clinical trial related services related to Phase II, III and IV clinical research including:

- Study-Site Feasibility Analysis
- Negotiating study budget and securing approval for Clinical Trial Agreement (CTA)
- Site set-up, Study initiation and Start-up activities
- Site Monitoring, Operations and Project Management
- Submission to Regulatory Authority
- Financial administration of study

***"Pleasure in the job puts perfection in the work, it's the result that matters"***



#### Contact

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Fax: +603-4041 2823

Website: <http://www.myxmo.com.my>



Veras Research provides Contract Research Organization services in Malaysia and the South East Asian region. The journey of Veras Research began with its sister company, Azmi Burhani Consulting which was established to provide research consulting, health economics and outcomes research services. Veras Research was created with a focus on clinical trials and primary data collection through late phase and observational studies. Veras Research (Malaysia) obtained Bionexus status from Biotech Corporation in 2010. We have registered offices in Singapore and the United States. Veras Research is also a founding member of the Asia CRO Alliance.

Our team is capable of handling projects from the point of idea development, strategy, protocol & CRF development all the way to study implementation and working with study sites. Our personnel strength is now 25 people. Upon permanent hire, our team is provided in-depth training of medical knowledge and research methods. Team capacity is constantly developed through coaching and training sessions.



### **Our services include:**

#### **Pre-study Planning & Feasibility Studies**

- Strategic pre-trial consulting
- Clinical trial feasibility studies
- Investigator & site selection

#### **Clinical Database Design**

- Design & database application
- Data security management & procedures development

#### **Regulatory Process Submission**

- Ethics committee submission
- Clinical Trial Import License
- Dossier submission

#### **Clinical Trial Management**

- Site initiation, monitoring & management
- Project management

#### **Study Design**

- Study design & protocol development
- Literature review & meta-analysis
- Case Report Form development
- Pharmacoeconomic studies

#### **Clinical Data Management**

- Data management plan
- Case Report Form retrieval & management
- Electronic data capture
- Data entry, cleaning & query
- Document archiving

#### **Biostatistics**

- Statistical planning & sample size estimation
- Statistical analysis

### **Medical Writing**

- CSR & manuscript development
- Translation

As we look forward to a great year in 2017, we hope that Malaysia and the South East Asian region will grow toward becoming a top destination for clinical trials and scientific data generation.

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**InnoSignum**  
Sdn. Bhd

InnoSignum was conceived when three like-minded clinical research and regulatory professionals came together to set up a company focusing on clinical research and regulatory services for medical device, biotechnology and pharmaceutical products.

Established in October 2015, InnoSignum Sdn Bhd initially started by providing regulatory and medical device registration services to both local and international companies. Over a year, its headcount grew and it started to provide clinical research services. The organization's core competencies and strength lies in its dynamic and energetic team, experienced with a broad background in clinical trials management in phase II/III/IV trials, registry, and various therapeutic areas.

With our combined experience of more than 20 years in clinical research, we understand the importance of cost and time as well as the technical quality of the result, and compliance with regulatory requirements. Our values - Dedication, Integrity, Innovation, Solidarity, Collaboration encompassed our service quality and continuous improvement.

As a young 'local' CRO, we started by providing clinical research services to small and medium medical device companies. We believe 'in doing the small things well'. Recently, our efforts and dedication was rewarded when Shanghai MicroPort Medical (Group) Co., Ltd awarded the company with a project to conduct a multicentre registry study in Malaysia. This breakthrough is a significant milestone for our company and will continue to drive us for effective and quality research delivery.



# CRM's Scope of Services

CRM currently provides the following services



## FEASIBILITY STUDIES & INVESTIGATOR MATCHING

- CRM evaluates feasibility studies / request that are forwarded by sponsors / CROs and disseminates them to a large pool of potential investigators
- CRM assist investigators who are interested to take-on the trial to complete and submit the feasibility study / request to the sponsor or CRO



## CONSULTATION AND MANAGEMENT OF CLINICAL TRIAL BUDGET

- CRM advises investigators and sponsors/CROs on the clinical trial budget. This service ensures that resources are sufficient in order to complete all obligations of the clinical trial.
- CRM manages the trial budget with full transparency and schedule reports to investigators and the sponsor/CRO (CRM charges a fee of 15% above the value of the trial budget which will be utilized to finance its operations and training programs to upskill investigators and support staff)



## REVIEW OF CTA & NDA

- CRM assists investigators & sponsors/CROs by reviewing and advising on Clinical Trial Agreements (CTAs) & Non-Disclosure Agreements (NDAs).
- CRM's experienced legal team will provide assistance to review the CTA/NDA.



## DEVELOPMENT & PLACEMENT OF STUDY COORDINATORS

- CRM recruits suitably qualified candidates and trains them to become capable Study Coordinators (SCs) who will then be placed at trial sites in order to assist investigators.
- CRM currently has more than 80 trained SCs based in major Clinical Research Centres nationwide.



## TRAINING RELATED TO CLINICAL RESEARCH

- CRM organizes various subsidized training programs for investigators and support staff in order to improve their capabilities to undertake ISR.
- Refresher courses on Good Clinical Practice (GCP) are also held for doctors and support staff.



## ONE-STOP CENTRE FOR THE INDUSTRY

- CRM assists industry players in resolving issues or delays faced with government agencies and regulators (e.g. BLESS, MREC, MDA, NPCB, IRBs) that may delay the approval or initiation of trials.



## SITES CAPABILITY IMPROVEMENT & ENHANCEMENT

- CRM improves the capability of sites by assisting in both systems and infrastructure improvements.



## IMPROVING PUBLIC AND PATIENT AWARENESS

- CRM engages with a variety of patient support groups and NGOs, undertakes advertising an promotional events, and seeks to generate positive media coverage to spread the word about clinical research, generate goodwill and to facilitate patient recruitment.



## GROWING THE POOL OF INVESTIGATORS AND SITES

- CRM continuously attracts and develops potential new investigators and sites in both the public & private healthcare system



## PROMOTING MALAYSIA AS A HUB FOR INDUSTRY SPONSORED RESEARCH (ISR)

- CRM participates in national and international events to engage sponsors and CROs as well as to promote Malaysia as a choice destination for ISR.



**Kitasato Clinical Research Center & CROs from Japan Visit,  
4th December**



**Phase 1 Clinical Trial Guideline Workshop,  
19th November**



**Institut Kesihatan Umum Visit to CRM HQ,  
6th September**



**CRM GCP Refresher Program (Internal),  
15th December**



**MoA Signing Between Aurigene & IMR Towards  
Collaborative Program, 8th December**



**NIH Research Week,  
19th - 23rd November**



**ECG & Basic Physical Measurement  
Workshop for Study Coordinator, 18th November**



**Selangor Research Day & Anniversary of  
Sungai Buloh Hospital, 7th - 8th September**



**2nd CRM Industry Dialogue 2016,  
25th October**





**Visit to Novo Nordisk, Copenhagen,  
8th October**



**Global AstraZeneca Team meeting  
with CRM, Copenhagen, 9th October**



**C&R Research Inc. Visit,  
6th - 9th September**



**ESMO Congress 2016,  
7th - 11th October**



**UK-Malaysia Collaboration on Health-  
care, UK experts visits, 9th November**



**Cervical Cancer Referral Programme Northern Region Meeting,  
2nd September**



**Recruiting Patients for Clinical Trials  
Trials Workshop, 22nd October**



**Bayer Visit to CRM,  
21st October**



**1st Hospital Kuala Lumpur  
Research Day, 22nd September**



**CTA Workshop for Sponsors & CROs,  
25th October**



**Hands on Training for CRC  
& CRM Study Coordinators  
(Northern), 16th - 18th November**



**2nd CRM Investigator's Dialogue 2016,  
22nd September**



**NERCIM 2016/2,  
9th November**



**Terengganu Research Day,  
28th September**



**Annual Scientific Conference  
Malaysians Oncology Society 2016,  
11th - 12th November**



# CONVERGENCE OF THE **GOVERNMENT,** SCIENCE AND INDUSTRY

Malaysia Is Developing Clinical Research  
as an Economic Growth Engine



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change  
tomorrow's  
healthcare

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