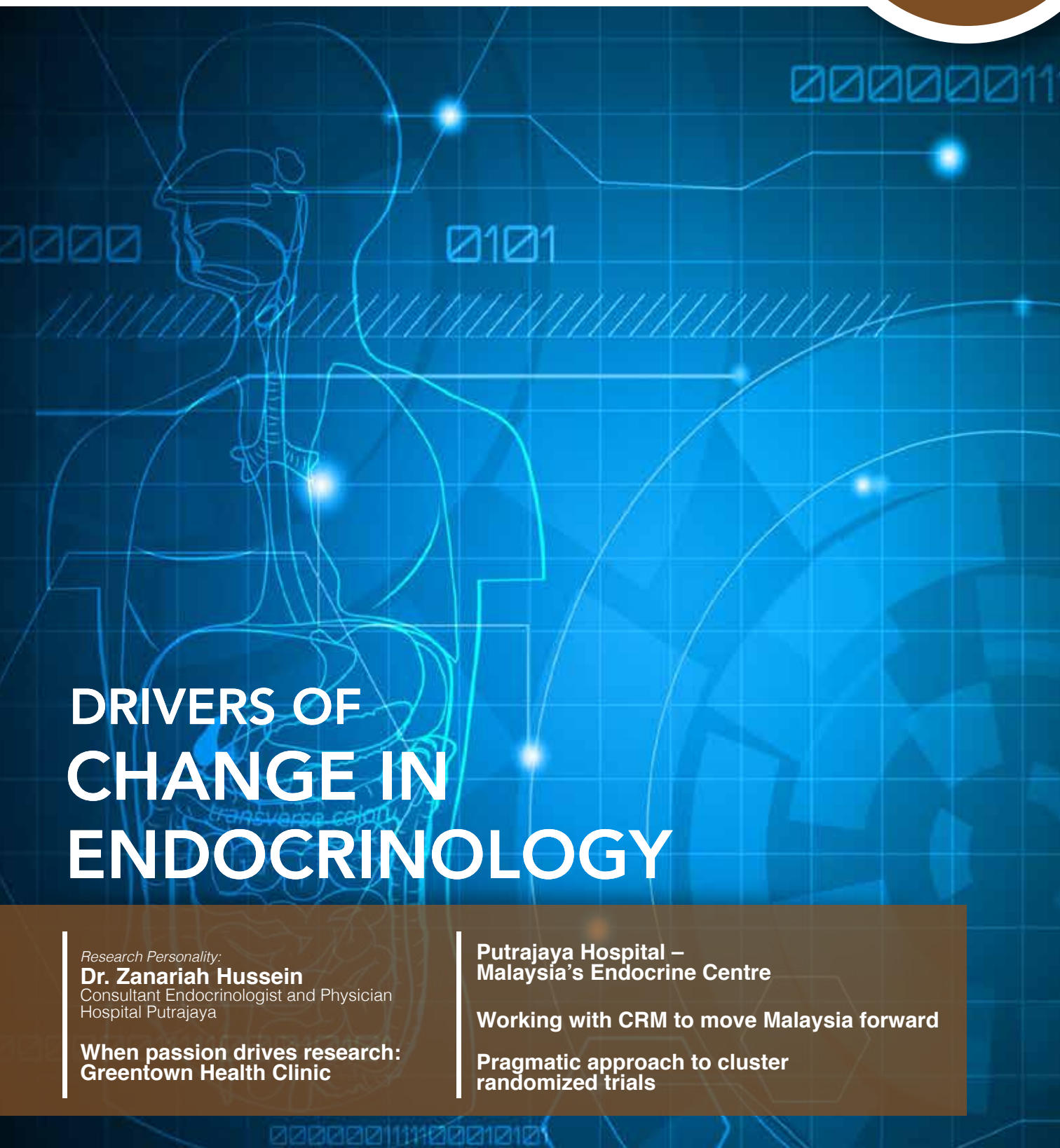
By Clinical Research Malaysia

CRM bulletin

of Clinical Research and Therapy

ISSUE 07



DRIVERS OF CHANGE IN ENDOCRINOLOGY

Research Personality:
Dr. Zanariah Hussein
Consultant Endocrinologist and Physician
Hospital Putrajaya

When passion drives research: Greentown Health Clinic

Putrajaya Hospital – Malaysia's Endocrine Centre

Working with CRM to move Malaysia forward

Pragmatic approach to cluster randomized trials

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.

MINISTRY OF HEALTH MALAYSIA

CLINICAL RESEARCH MALAYSIA

Your Global Solutions in One Nation

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From the CEO's desk

Welcome to the seventh issue of the CRM bulletin. Once again, there are many interesting articles based on the theme for this issue – Endocrinology. Endocrinology trials in Malaysia account as the third largest number of industry sponsored studies by therapeutic area, and of these, diabetes forms the highest number of trials. It was just a month ago that the world over celebrated World Diabetes Day.

Diabetes has long been a key national interest due to the wide-ranging costs for individuals, families and healthcare systems inflicted by this disease. It threatens to undermine economic growth, particularly in developing countries, which currently shoulder most of the diabetes burden. In fact, Malaysia tops the list in South-East Asia for having the highest prevalence of diabetes in this region. The International Diabetes Federation (IDF) and World Health Organization (WHO) figures indicate that over 387 million people now have diabetes worldwide. This number is set to reach 552 million by 2030 if significant action is not taken to tackle this growing epidemic. In Malaysia alone, 16.6% or 3.2 million adults between 20 and 79 years are diabetic; that's about 1 in every 6 adults.

In essence, diabetes clinical trials are an essential part of the development of new interventions and tests that may help to improve ones diabetes or improve the health care of others.

When we conduct or participate in clinical trials, we help move our research ahead faster, and that means timelines for better devices, drugs, and services for diabetes management are shorter. Investigators that conduct clinical trials tend to be better researchers while patients that participate in these studies tend to have better control and management of their condition due to regular follow-ups and careful monitoring of experts in this disease. However, this is not confined to diabetes alone, but encompass all types of diseases and conditions.

CRM will remain committed in creating an ideal ecosystem for clinical research in hopes of bringing in more industry sponsored research studies to our shores so that Malaysians can benefit from the most advanced treatment methods and cutting edge therapies available. As we approach the end of yet another year, I'd like to thank all of you for your support as we continue to work towards making Malaysia the hub for clinical research.

Finally, I hope you find this issue of the CRM bulletin both informative and useful. Have an enjoyable read.

Thank you.

Dr. Akhmal Yusof
Chief Executive Officer
Clinical Research Malaysia

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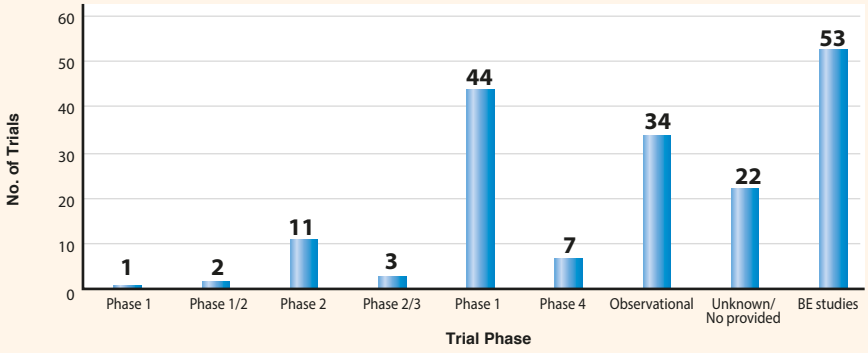
MALAYSIA'S ISR STATISTICS (JAN – OCT '15)

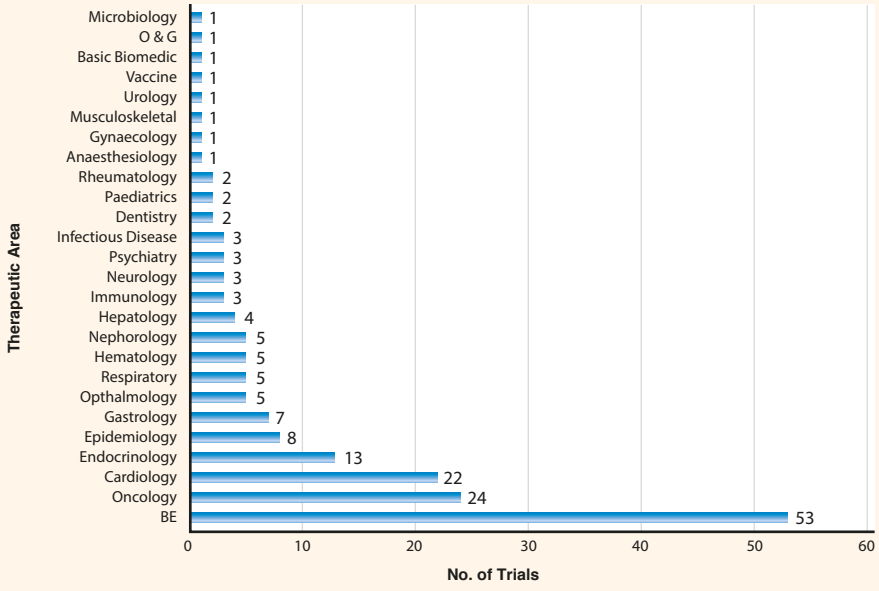


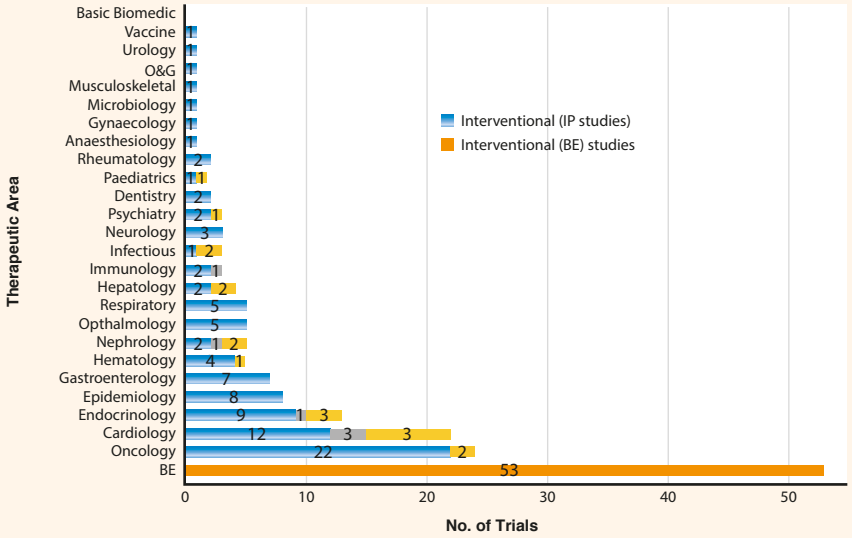
Jan – Oct 2015: Trials Approved by Ethics Committees According to Phase

A total of 177 trials were approved between January and October 2015. Of the total, 163 are ISR trials and 14 are hybrid studies.

Jan – Oct 2015: Trials Approved by Ethics Committees According to Therapeutic Area

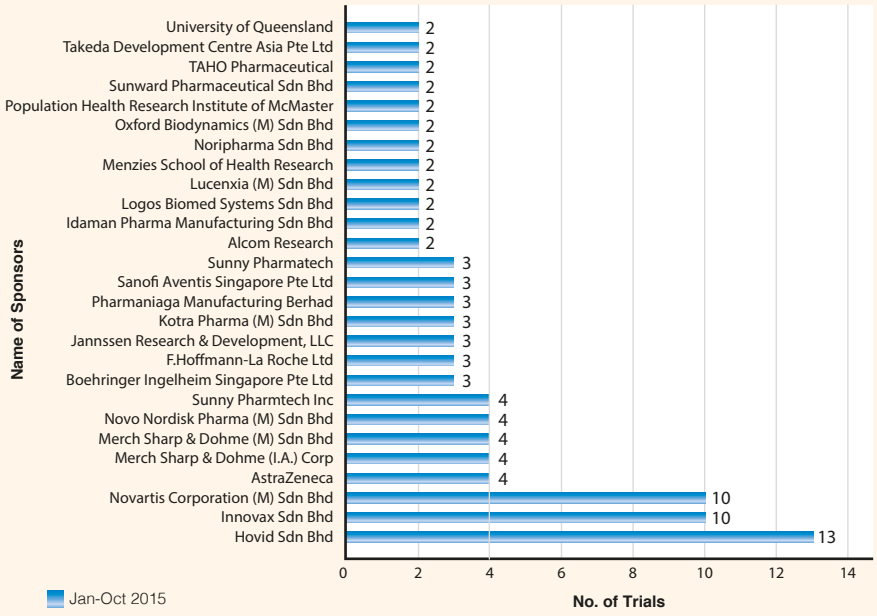
Oncology trials accounted for 24 trials, followed by cardiology with 22 trials and endocrinology with 13 trials.





Jan – Oct 2015: Trials Approved by Ethics Committees According to Therapeutic Area & Classification

Majority of the trials conducted were interventional trials of new investigational product (IP), followed by interventional bioequivalence (BE) studies, observational studies and medical device studies.



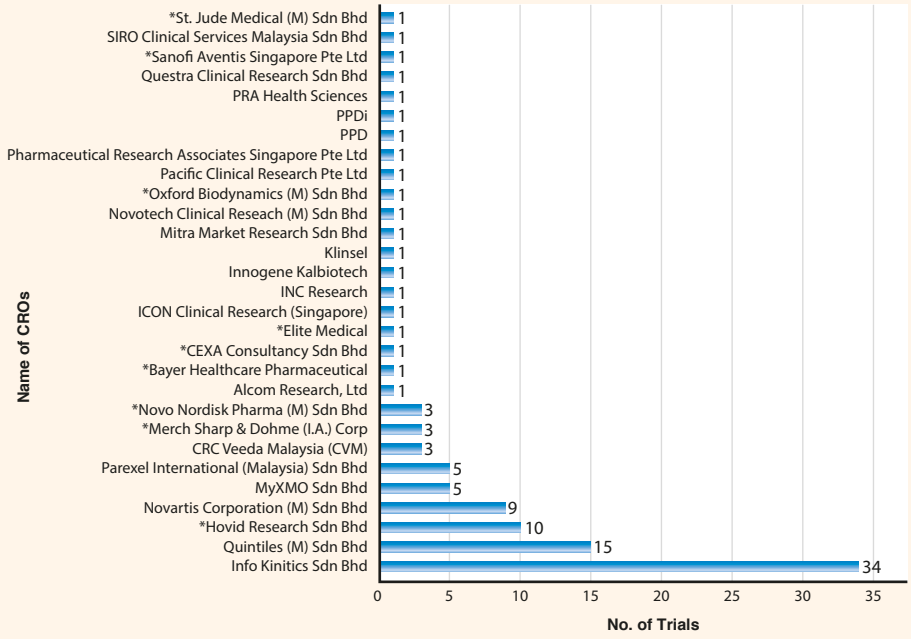
Jan – Oct 2015: Number of Approved (New) Trials According to Sponsor

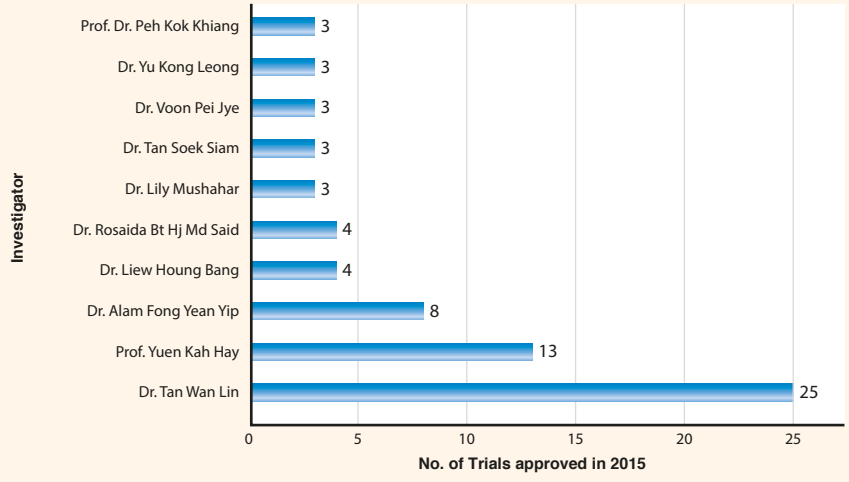
Hovid Sdn Bhd recorded the highest number of approved trials in 2015, followed by Innovax Sdn Bhd and Novartis Corporation (M) Sdn Bhd.

Jan – Oct 2015: Number of Approved (New) Trials According to CROs

Info Kinetics Sdn Bhd recorded the highest number of approved trials in 2015, followed by Quintiles (M) Sdn Bhd and Hovid Research Sdn Bhd.

Note: *Depicts Sponsor who have their own 'CRO' arm to manage the trial conduct





Top 10 Active Investigators in 2015

(based on number of new trials approved from Jan-Oct 2015)

MEDICAL RESEARCH AND ETHICS COMMITTEE (MREC) UPDATES

Clinical Research Malaysia (CRM) recently organized the 2nd Industry Dialogue which was attended by representatives from contract research organizations, sponsors and other stakeholders from the clinical research industry. The aim of the dialogue was to provide an avenue for these relevant parties to discuss issues faced within the clinical research environment as well as to get updates from the ethics and regulatory authorities in Malaysia. Dr Gurpreet Kaur, the MREC Secretary, updated the participants on the recent changes to the NMRR system and the approval timeline for industry sponsored research.

Initial Approval Submission

Effective March 2015, Study Investigator (SI) /Corresponding Person (CP) is able to monitor study progress or decision points in NMRR website once the study is forwarded to MREC and they would be able to view the current status of the study.

NMRR has also came out with a review checklist for protocol/patient information sheet (PIS) which is only applicable for new submissions of interventional studies. With this, all new applications to MREC must complete and upload the review checklist in the relevant section under 'Research Documents'.

Effective January 2015, MREC has revised the initial revision timeline from 30 working days to 20 working days and the re-evaluation of revised submission timeline from 20 working days to 10 working days, thus cutting down its approval timeline by one month (Table 1).

Table 1. Comparison between the previous and recently revised MREC approval timeline (Effective January 2015)

No.	Description	Previous Timeline (2014)	Revised Timeline (Effective Jan 2015)
1	**MREC INITIAL APPROVAL: Timeline begins from date of NMRR ID issues (provided completed study submission has been made to MREC via NMRR)**		
a	Study is forwarded to MREC ⟶ MREC Review	At least 10 working days*	At least 10 working days*
b	MREC ⟶ MREC Decision Letter (Approval/ Disapproval/ Revision required)	10 working days	10 working days
c	If revision required (Revision of study documents by PI/CP upon receipt of follow-up review report and MREC comment letter)	30 working days	20 working days
d	Study resubmission by PI/CP ⟶ MREC decision* (Provided all queries by MREC have been answered)	20 working days	10 working days
2	**SUBMISSION POST MREC INITIAL APPROVAL: Submission must be uploaded in NMRR. Timeline begins from the last date of submission by corresponding person**		
a	Amendments that are non-substantial/less than minimal risk, submission of final study report, submission of study termination memorandum.	20 working days	20 working days
b	Substantial amendments, submission for MREC ethical renewal.	30 working days	30 working days

*Valid for studies that are to be re-evaluated by Chairman/Secretary alone. If the study is required to be re-evaluated by primary reviewers or in a full-board meeting the re-evaluation period may be longer.

Please take note that the timelines stated is for guideline purposes only. These processing timelines may vary on a case to case basis depending on the availability of the MREC Secretariat, MREC reviewers or any other unforeseen circumstances.
CP = corresponding person; PI = principal investigator; SAE = severe adverse effect; SUSAR = suspected unexpected serious adverse reaction.

Note: In the event where a study is revised following its initial submission, the last submission date of the revised study will be taken and not the date of the first initial submission.

Amendments
Effective April 2015, MREC introduced a new amendment form which is called Amendment Application Form to facilitate the screening and review process. The form is to be uploaded by the PI/CP, when submitting new amendments, in the designated section in the NMRR website.

MREC Ethical Renewal
Effective since March 2015, the NMRR website has a new function tab to upload study Continuing Review Form. Approval by MREC is valid for a period of up to one year. The details on MREC approval expiry date can be found in the MREC Initial Approval Letter or MREC Ethical Renewal letter. To ensure continuity of ethical approval, PI/CP must submit the Continuing Review Form to MREC at least two months before expiry of MREC approval. Failure to submit the Continuing Review Form within the stated period will result in a delay in reviewing, issuing the ethical renewal letter and gaps in the ethical approval period. MREC will not back date any approval prior to the submission or review date.

Notifications – AOR Function
All documents for the purpose of MREC Notification and Acknowledgement of Receipt (AOR) needs to be uploaded in the NMRR system effective January 2015. MREC would no longer be acknowledging documents received via e-mail, fax or courier/mail. Up to 32 different documents can be uploaded at a single submission and multiple submissions could be made to MREC at any given time. Upon complete submission via NMRR, an acknowledgement e-mail by NMRR will be sent to the Study Corresponding Person/Corresponding Back-up person. This is not to be confused with amendment submission which is separate and usually involves a decision letter by MREC.

Notifications – Protocol Deviation
Protocol deviations/ violations needs to be reported using the MREC Protocol Violation and Deviation Report and not in any other format. Each incident requires a separate report to be submitted. Currently we require a description of the Protocol Deviation/ Violation Event to be included in the 'Notes to MREC Secretariat' in NMRR when submitting protocol deviation reports until further upgrades to the system.

Notifications – SAE/SUSAR
Among the SAE/SUSAR issues that MREC have noted include incomplete SAE reports (not following the minimum requirements), delayed reporting, follow-up reports not provided, type of report not indicated (i.e. initial or follow-up), delayed response after feedback from MREC, inadequate details provided in SAE report and illegible handwriting.

Study Completion/ Termination
A new function tab is made available effective March 2015 in NMRR to upload Study Final Report and Study Termination Memorandum. The Study Final Report is to be submitted within 2 months upon study completion while the Study Termination Memorandum is to be submitted once the PI is notified about the study termination.

MREC FAQs

Is trial insurance needed for initial submission/review? Can it be submitted later?

Yes, trial insurance is required if the study is of clinical trial or BA/BE and it needs to be submitted with the initial submission. It cannot be submitted later.

Is the Malay Translated Patient Information Sheet (PIS)/ Inform Consent Form (ICF) needed?

Both English and Malay Language PIS/ICF are required by MREC. In the event the targeted population is such that the Malay ICFs would not be required at all, a clear justification for this needs to be submitted for MREC first to decide if it is allowed.

Does the study Principal Investigator (PI) need to attend the MREC full-board review meeting?

Study PI is no longer required to attend MREC full-board review meetings unless specific requests are made by the MREC reviewers. If needed, the Secretariat will be communicating with the study PI at least 2 working days prior to the meeting. If the PI is unable to attend, the Secretariat would make arrangements for a teleconference/ SKYPE session with the PI.

How soon will the PI be informed on the decision after MREC full-board review meeting?

The study PI will be informed on the decision within 10 working days after the meeting. Should there be a delay (due to the need for added review/ clarifications after the meeting), the MREC Secretary will be communicating to the study PI on the matter.

RESEARCH PERSONALITY

Dr. Zanariah Hussein

Consultant Endocrinologist and Physician
Hospital Putrajaya

Dr. Zanariah Hussein is a Consultant Endocrinologist and Physician at Hospital Putrajaya, where she is the Head of the Endocrinology Subspecialty Service. She obtained an MBBS from the University of Malaya and an MRCP from Edinburgh, UK. She holds various educational administrative positions including the Chairperson for the Endocrine Fellowship Training Program, Honorary Lecturer at the Faculty of Medicine UiTM, UKM and UM as well as a member and Ministry of Health representative for the Specialty Conjoint Board for Masters of Internal Medicine.

Dr. Zanariah is an active member in the Malaysian Endocrine and Metabolic Society, Asia Pacific Neuroendocrine Tumour Society, National Diabetes Institute, The Endocrine Society, USA, and the American Association of Clinical Endocrinologists. She is and has been an Investigator and Co-Investigator in over 40 mulicentre clinical trials and has published over 50 national and international peer reviewed journals.

Despite the many hats she wears and the international recognition for her research contributions, Dr. Zanariah remains a humble and down-to-earth clinician. She recently shared with CRM about her experience running clinical trials.

Can you describe when and how you first got involved in clinical trials?

My first experience with clinical trials was when I was training as a fellow in endocrinology, in 1998, whereby my then supervisor was involved in a diabetes trial at Hospital Kuala Lumpur (HKL). I subsequently became a sub-investigator in one of the trials when I was pursuing my postgraduate training at Hospital Universiti Kebangsaan Malaysia (HUKM) and began taking the role of a principal investigator (PI) when I was called to serve at Hospital Putrajaya.

How do you divide your time between clinical practice and conducting trials?

In the beginning it was not too difficult because I was a co-investigator and did not have much responsibility. In addition, the number of trials at that time was perhaps, one a year. In recent years, the number of trials at Hospital Putrajaya has seen an increase, but with a dedicated team of study coordinators, I managed to press on and have allocated different days for performing research and clinic duties.

Our team consists of 4 consultant endocrinologists who are PIs and co-investigators. Recently, we have assigned one or two specialist physician trainees into several clinical studies. In the past we had to look for our own study coordinators and we did not have a Clinical Research Centre (CRC).

We hired our own study coordinators but also had our diabetes nurses helping us. This was difficult because they had other roles to play. But with an established CRC and study coordinators who are 100 percent dedicated to clinical trials, it has been superb.

What are the challenges that you face when conducting a clinical trial?

The challenge is trying to get other members of the team to be as enthusiastic about the trial as you are. You have to ensure equal participation and it can be difficult because everybody has different roles to play. Before having my own study coordinators, I would have to key data into the electronic case report form all by myself. But now, with a dedicated and supportive study team, clinical trials has become much more manageable.

How does your patient respond when asked to participate in a clinical trial?

There are a group of patients who have been with us for a long time and usually they are seen to be the ones we fall back on when we have trials. We are lucky to have progressed over the decades having some of the same patients being involved and are very eager to be involved again. Of course those who have never participated in clinical trials before will appear apprehensive at first when we approach them. Effective communication with patients is not just about delivering the right information. It is also about anticipating their needs and being mindful of their different perspectives and knowledge.

Can you tell us how has your patients benefited from participating in a clinical trial?

Those who have participated in a trial become more in tune with their disease and up-to-date with the administered therapies. Apart from running diabetes trials, other endocrine-related trials that are conducted in Putrajaya Hospital include Cushing's disease, acromegaly, and growth hormone deficiency. We encourage trials of rare diseases to be conducted here as there is none such at the moment. Our team has managed to fulfil the requirements for the Cushing's disease trial and the patients that are on this trial were given the opportunity to receive the most up-to-date therapy. Patients would suffer if they were to wait until a new/improved drug is marketed.

What is your motivation behind conducting clinical trials?

My motivation comes from the opportunity to perform the most ideal of practice, and keeping up to date with the current ways of managing disease. This has been the reason to pursue that, and also to get the other team members to embark on this rewarding journey. Through good clinical practice (GCP), one learns to handle clinical trials the right way and this include proper handling of records and ensuring that adverse events are recorded and handled appropriately. These good practices and habits can be translated into one's clinical practice.

In your opinion, what are the necessary qualities of a Principal investigator?

Principal investigators must be interested and committed in conducting clinical trials as it usually demands a lot of their time. They must believe that their efforts can ultimately contribute to the development of new therapies.

What do you see are the strengths of Hospital Putrajaya when it comes to conducting clinical trials?

Putrajaya Hospital has the experience in conducting clinical trials even though it has only been in operation since 2001. One of our strength includes having the experience of managing diabetes trials for more than a decade. We have 4 endocrinologists and an established CRC. These factors are paramount in building the reputation of the site to encourage industry sponsored research. Looking forward, we want to develop Putrajaya Hospital as a site for other endocrine trials and to work towards building our reputation in Southeast Asia.

Why do you think it is important for a clinician to get involved in clinical trials?

Clinical trials can improve a clinician's overall career and profession. It keeps you up-to-date with the latest medical technology and therapies and by getting involved, clinicians will be at the forefront of medicine in the area that they specialize in, especially with newer drugs and interventions. They will have the benefit of being at the cutting edge of medicine, have the privilege of knowing what is coming up in the future and being able to participate in discussions with internationally recognized experts in the field. This will translate into a better understanding of the disease and no doubt improve a clinician's clinical practice.

Do you have any personal dreams or goals that you strive to achieve?

I was never that ambitious and only wanted to be a small time general practitioner in the early days. Somehow, our goals tend to evolve with time and once we find an area of interest, you may just want to do more. But I think what's most important is to try and make a difference in this world.

Dr. Zanariah with one of her clinical trial participant

Dr. Zanariah and her research team

DIABETES BY THE NUMBERS

387 million

387 million people have diabetes globally

552 million

552 million people will be affected by 2030

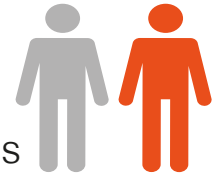
Every **7 SECONDS**

1 person **dies from diabetes**

4.8 million DEATHS

due to diabetes in 2014

1 in **2**



people with diabetes **DO NOT KNOW** they have it

Diabetes in Malaysia in 2014

Prevalence of diabetes in adults (20–79 years)

3.2 million or 16.6%

That's about 1 out of every 6 adults

Number of cases of diabetes in adults that are undiagnosed

1.717 million undiagnosed

34,422 Number of deaths in **ADULTS** 20–79 years **due to diabetes**

The Global Burden

11%

of total healthcare expenditure in the world is attributed to diabetes-related costs

USD 548 billion

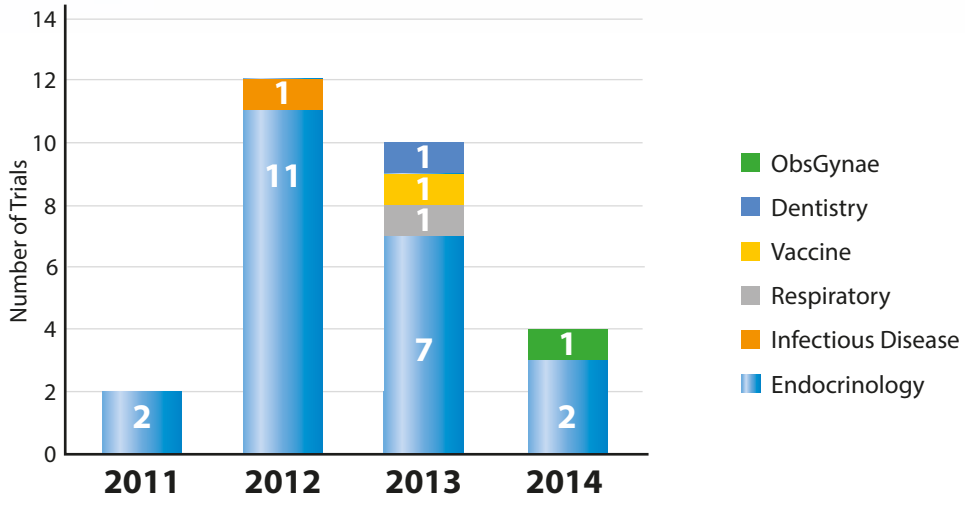
Diabetes takes up some USD 548 billion in health spending

77% of people with diabetes live in low-and middle-income countries

Source: International Diabetes Federation

INDUSTRY SPONSORED RESEARCH: OF SITES, INVESTIGATORS AND THERAPEUTIC AREAS

ISR by FMS: Therapeutic Classification



Top 5 Family Medicine Specialist Conducting Clinical Trials in Malaysia

Top 5 Family Medicine Specialist	Number of ISR	Site
Dr V. Paranthaman	10	Klinik Kesihatan Greentown
Dr Sree Kantan Nayar P.K.S. Nayar	8	Klinik Kesihatan Greentown
Dr Sri Wahyu Taher	6	Klinik Kesihatan Simpang Kuala
Dr Mastura Ismail	4	Klinik Kesihatan Seremban 2
Dr Norsiah bt Ali	4	Klinik Kesihatan Tampin

Most Active Sites for Industry Sponsored Research in Malaysia

Therapeutic Area	Most Active Site for ISR	Therapeutic Area	Most Active Site for ISR
Anaesthesiology	Hospital Kuala Lumpur	Nephrology	Hospital Pulau Pinang
Cardiovascular	Hospital Umum Sarawak	Neurology	Hospital Kuala Lumpur
Dermatology	Hospital Kuala Lumpur	Obstetrics & Gynaecology	Hospital Wanita dan Kanak-Kanak Sabah
Dietetics & Nutrition	Hospital Selayang	Oncology - Clinical	Hospital Kuala Lumpur
Emergency Medicine	Hospital Umum Sarawak	Ophthalmology	Hospital Umum Sarawak
Endocrinology	Hospital Putrajaya	Orthopaedic	Hospital Pulau Pinang
Family medicine	Klinik Kesihatan Greentown	Paediatrics - General	Hospital Umum Sarawak
Gastroenterology	Hospital Sultanah Bahiyah	Psychiatry	Hospital Permai
Haematology	Hospital Ampang	Respiratory	Hospital Pulau Pinang
Hepatology	Hospital Selayang	Rheumatology	Hospital Selayang
Infectious Disease	Hospital Sungai Buloh	Urology	Hospital Kuala Lumpur

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We know that our products only get us part of the way. We work with partners across the haemophilia community in order to reach our goals. Changing Possibilities in Haemophilia® is our response to address the unmet needs in haemophilia care.

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MSB/CH/0815/0144

JISVINA PRIT KAUR
Jisvina has type 1 diabetes
Malaysia

changing diabetes®

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Through collaboration with individuals, organisations and governments, we work to advance diabetes to the top of the global health agenda.

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Please refer to Appendix for Abbreviated Prescribing Information.
MSB/CD/0815/0398

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WHEN PASSION DRIVES RESEARCH: GREENTOWN HEALTH CLINIC, IPOH

Dr. Sree Kantan Nayar

Senior Medical Officer and Clinical Coordinator
Greentown Health Clinic, Ipoh

Dr. Sree Kantan Nayar is a Senior Medical Officer and Clinical Coordinator at Greentown Health Clinic, Ipoh, more popularly known as Klinik Kesihatan Greentown. He has over 20 years' experience as a clinician with stints as a medical officer throughout the state of Perak and in Kuala Lumpur. He is involved in training medical students and housemen, running of a high risk clinic and conducting his own as well as industry sponsored research among others.

Even with his vast experience, clinical trials were not something that came naturally to him. He stumbled upon the idea of conducting trials when he worked with Dr. G.R. Letchuman, a renowned Consultant Physician and Endocrinologist. He was a medical officer at the clinic of the Medical Unit, Hospital Raja Permaisuri Bainun, Ipoh at the time.

In 2003, Dr. Letchuman had asked him if he was interested to participate in a clinical trial. He gave it a go and as they say, the rest is history. When the nascent team first embarked on a clinical trial, they found that research required a higher level of attention to details. Everything they did had to be scrutinized under a microscope. On reflection, Dr. Sree believed that his personality suited research, as he always had a keen eye for little details.

Initially, clinical trials were run at the outpatient clinic with Dr. Letchuman as the principal investigator and Dr. Sree assisting as co-investigator. But Dr. Letchuman had always intended to pass on the baton as he wanted to focus more of his time at Hospital Raja Permaisuri Bainun. Coincidentally the outpatient clinic was moved from the hospital to a brand new, separate facility nearby, Klinik Kesihatan Greentown. A few years after the move, Dr. Sree took over as principal investigator.

In 2004, Klinik Kesihatan Greentown was one of only a few government clinics to participate in industry-sponsored clinical trials. This surprised many doctors at investigator meetings. Many doctors had the idea that a government clinic is crowded, noisy and haphazard, and wondered how they managed to maintain the nice, tidy order required of a clinical trial. But against all odds, they persevered.

INVESTING in people

Dr. Sree credits the pioneering staff for getting the clinical trial ball rolling. Starting with a small crew comprising himself, Dr. Letchuman, and a retired nurse, Ms. Wong Kheng Chee, they rolled up their sleeves to set up the location and recruit patients. Dr. Sree commends Ms. Wong, who is still actively involved in his research team for her efficiency, dedication and her rapport with the patients. They also received support from a nurse sister, Sister Mariaman in the earlier stages of setting up the trial site.

When participating in a clinical trial, managing finances has to be done in a transparent manner and the team is held accountable for all money coming in and out of the account. Dr. Sree was thankful that they had help from the hospital to manage their accounts, in the earlier days. But he realized the need for a person dedicated to managing their accounts, and that was when Mrs. Preet Kaur was roped into the team to do just that.

In its infancy, the Klinik Kesihatan (KK) did not have clinical specialists. It was only recently that family medicine specialists (FMS) were stationed at Klinik Kesihatan. The budding team was actually guided by physicians from the hospital. Dr. V. Paranthaman, an FMS from Jelapang was roped in because he had shown an interest in clinical trials. He is now a principal investigator for the Greentown site. Dr. Sree credits Dr. Amilia Hazreen, an FMS stationed at KK Greentown who is a sub-investigator for her hard work and professionalism. He also acknowledged Dr. Subashini Ambigapathy, who was a principal investigator for the site but has since moved on, and Dr. Lau Kin Mun, a sub-investigator. He could not have imagined achieving success without their efforts.

Part of the reason the Greentown site was successful was the large pool of diabetic and hypertensive patients from Klinik Kesihatan Greentown, Ipoh. The hospital had close to 10,000 patients that could participate in studies that involved diabetes, dyslipidaemia and hypertension. The proximity to the hospital allowed them access to this cohort of patients. Dr. Sree is proud of the fact that the Greentown site was one of a few sites in the world to participate in the phase 3 trial of the DPP-4 inhibitor drug, Januvia (sitagliptin). He said research kept the site at the cutting-edge of medicine.

Advice to young doctors

Dr. Sree said doctors should participate in clinical trials to give their patients access to the best possible treatment and management of their disease. Even within the constraints of government service, good quality treatment does not always involve a lot of money.

Young doctors who are keen to take part in clinical trials should have very good knowledge of their field of interest. Dr. Sree pointed out that clinical trials requires hard work and doctors must be willing to put in the hours. He shared that when he just started out, he used to go home around 8–9pm but he assures doctors that it gets easier with time.

Finally, Dr. Sree discussed the type of support that is important for a doctor who wants to conduct clinical trials. Having support from colleagues is important but most importantly is to have supportive superiors, which he did have throughout his years participating in clinical trials.

CRM bulletin

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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

PUTRAJAYA HOSPITAL: MALAYSIA'S ENDOCRINE CENTRE

PUTRAJAYA HOSPITAL:

Putrajaya Hospital is a model hospital, located in the government administrative area of Putrajaya. The hospital provides secondary level care to the community. Its mission is to be a team of committed, caring and dynamic professionals, working in partnership with the community to promote quality care through mutual satisfaction and respect.

PUTRAJAYA HOSPITAL:

341 Beds

189 Dedicated Medical Officers

611 Nurses

79 Skilled Specialists

Therapeutic Areas of ISR at Hospital Putrajaya

- *Endocrinology*
- *Rheumatology*
- *Paediatric Endocrinology*
- *Orthopaedic*
- *ENT*
- *Pathology*

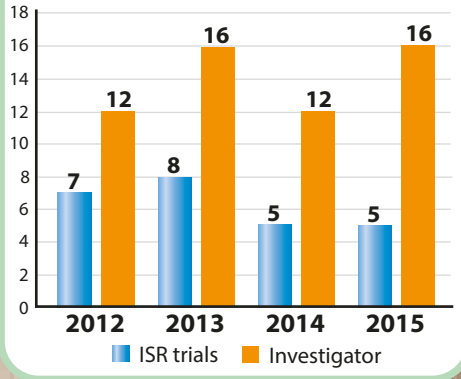
Principal Investigators

Dr. Zanariah Hussein (Endocrinology)
Dr. Nurain Mohd Noor (Endocrinology)
Dr. Masni Mohamad (Endocrinology)
Dr. Loh Vooi Lee (Endocrinology)
Dr. Loh Leh Teng (Endocrinology)
Dr. Loh Huai Heng (Endocrinology)
Dr. Tong Chin Voon (Endocrinology)
Dr. Wan Juani Wan Seman (Endocrinology)
Dr. Subashini Rajoo (Endocrinology)
Dr. Norfazillah Ab Manan (Endocrinology)
Dr. Lim Kah Yen (Endocrinology)
Dr. Shalena Nesaratnam (Endocrinology)
Dr. Azraii Nasruddin Bahari (Endocrinology)
Dr. Rafhati Adyani (Endocrinology)
Dr. Raudah Abd Rahman (Endocrinology)
Dr. Lisa Md Nor (Endocrinology)
Dr. Heselynn Hussein (Rheumatology)
Dr. Liza Mohd Isa (Rheumatology)
Dr. Norshuhaila Shahril (Rheumatology)
Dr. Shamala Rajalingam (Rheumatology)
Dr. Eashwary (Rheumatology)
Dr. Janet Hong Yeow Hua (Paediatric Endocrinology)
Dr. Fuziah Md Zain (Paediatric Endocrinology)
Dr. Jeanne (Paediatric Endocrinology)
Dr. Malik Faris Reza Feisal Jeffrizal (Rheumatology)
Dr. Ahmad Zaidi Othman (Rheumatology)
Dr. Foong Tuck Shin (Orthopaedic)
Dr. Chandran (Orthopaedic)
Dr. Balwinder Singh (ENT)
Dr. Siti Sharina Anas (Pathology)

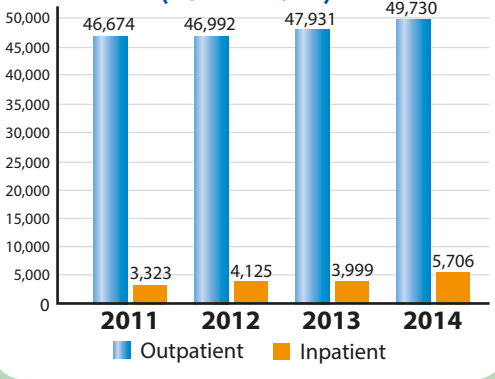
CRC

The Clinical Research Centre (CRC) at Hospital Putrajaya was established at the end of 2010. It was chosen as a Centre of Excellence to help and encourage Industry Sponsored Research (ISR) and at the same time to assist the Ministry of Health in achieving the Key Performance Indicator as targeted by the National Key Economic Area. The CRC at Hospital Putrajaya supports, coordinates and monitors all types of research including Investigator Initiated Research (IIR) and Industry Sponsored Research.

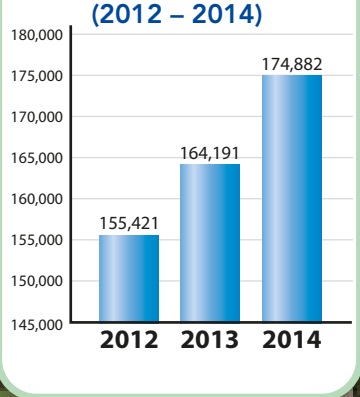
Total number of ISR and Investigators (2012 – 2015)



Average Inpatient Visits (2011 – 2014)



Specialist Clinic Visits (2012 – 2014)



WORKING WITH CRM TO MOVE MALAYSIA FORWARD

By George Clinical / 21 October, 2015

The Malaysian government has committed funding to improve the healthcare systems in order to further support clinical research. Clinical Research Malaysia (CRM) is a non-profit organisation – wholly owned by the government of Malaysia, which intends to develop infrastructure for the Clinical Research Centre networks, and be able to support global industry sponsored research (ISR) requirements. Recently, CRM appointed a new CEO, Dr Akhmal Yusof, who held individual meetings with various industry sponsors and CROs to promote the services provided by CRM. George Clinical Malaysia (GCM) was one of the CROs invited to participate. In addition to this, Dr Akhmal met with MOH investigators and institution directors to promote clinical research, as well as discuss ways to improve facilities and resources available to conduct clinical research.

To date, Malaysia has more than 80 ISR trial sites which have been approved by the Ministry of Health (MOH) and consists of an amalgamation of public and private hospitals. At the end of 2014, 202 new ISR trials were approved by the institutional review board (IRB). CRM targets 214 new trials for 2015, and their vision for 2020 is to conduct 1000 ongoing trials in Malaysia.

George Clinical Malaysia met with Dr Akhmal and discussed about initiating improvements to the site contracting process – in particular improving ethics approval timelines, which is currently one of the most time consuming hurdles for site start up. In order to alleviate this situation, CRM is in discussion with their legal officers along with the MOH legal advisor officer to update a bipartite clinical trial agreement (CTA) template for MOH sites. In addition, Malaysia recently introduced the goods and services tax (GST) which has affected the CTA and budget. To ensure smooth implementation of GST, CRM developed a CTA addendum for this GST clause. George Clinical Malaysia also suggested to CRM to construct a comprehensive database on patient populations for dedicated therapeutic areas at all MOH sites. This database will facilitate feasibilities and reduce start up timelines, as well as attract the industry.

Dr. Akhmal laid out five key strategies that has been the focus of CRM; grow the number of Principal Investigators and sites, attract new ISRs to Malaysia, enhance cooperation and collaboration with the stakeholders, create awareness of CRM among the medical fraternity, public and patients, and lastly, commit to developing human capital.

CRM has invested heavily in improving the facilities at the various clinical research sites as well as sponsoring Investigator's Award in conjunction with the State Research Day. These initiatives were undertaken to grow the number of investigators and sites. Apart from this, CRM has improved the efficiency of its feasibility process by creating a dedicated database of PIs. This effort improved the number of feasibilities by 300% compared to previous years, with a 50% growth in new Sponsors. By actively participating in national and international conferences and exhibitions, CRM managed to create awareness among the local and foreign industry players. This resulted in a 200% growth in inquiries from interested parties about ISR opportunities in Malaysia.

As one of Malaysia's key hurdles being the lack of quality resources in comparison to international standards, CRM has initiated refresher courses for MOH investigators and Study Coordinators. George Clinical Malaysia actively works with Principal Investigators to share information on these trainings to new investigators or unexperienced Study Coordinators. As a result of this, sponsors and CROs will gain a greater sense of assurance that Malaysia possess the necessary skills to conduct various clinical trials, while delivering a service of high quality.

About
George Clinical Malaysia

George Clinical Malaysia was established in 2009 and since then has consistently delivered on some of our largest programs. Based in Kuala Lumpur, George Clinical Malaysia also covers neighbouring South East Asian countries such as Singapore and Indonesia. We have established networks of cardio-vascular, diabetes and renal Investigators in this multi-racial country which has significant invest-ments into raising its profile as a clinical research destination.

GEORGE CLINICAL
Scientific and Operational Excellence in Clinical Trials

PRAGMATIC APPROACH TO CLUSTER RANDOMIZED TRIALS – A PERSPECTIVE FROM HEADPOST

Cluster randomized trials (CRTs) is the concept of grouping individuals for randomization into a treatment or control group. The design is increasingly becoming more common when randomizing large groups. It also reduces bias as there are less decision making required from clinicians or nurses.

A study to compare the effects of a patients head position after suffering a stroke (HeadPoST) is currently ongoing and has implemented the CRT design. The study has been designed to resolve the uncertainty of which head position is best suited for patients who have suffered acute stroke; and provide evidence to support a policy regarding the ideal head position in the acute phase of stroke. HeadPoST is the largest nursing care trial to be conducted with the target sample size of over 19,000 patients.
Although CRTs may seem complicated to treat/randomize, the nurses participating in HeadPoST were able to minimize errors that would disrupt the study by applying simple, yet effective procedures on-site.

Previously, a HeadPoST pilot study was conducted which clustered patients by months. Nurses participating in the pilot study were required to memorize the month and position their patients were positioned in. This was difficult to manage, so in the current full-scale HeadPoST study, the cluster was changed to sites rather than months – with an objective to reach 120 sites around the world for the trial to be effective.

The crossover from one head position to the next was at 50 ischemic stroke patients, and this had to be managed tightly. Once 48 ischemic stroke patients were achieved, the project team and sites would receive an alert to prepare for crossover. With the implementation of this new design, the patients head position remains the same until the next crossover – thus all patients had the same head position at any one time. Nurses only had to look at another patient in the ward to determine which head position was current. Nurses would also simplify the crossover procedure by placing posters above the patient's bed-heads to assist them in identifying the patients current head position for the trial. At this stage the crossover process has worked fluently with minimal late crossovers (approximately 3 out of 1900).

One of the challenges in HeadPost was the consecutive recruitment in the trial. Typical CRTs have washout periods to minimize contamination between clusters; however, in HeadPoST, subjects were recruited consecutively so that the momentum for recruitment was not lost. This resulted in an average recruitment rate of 7 subjects/site/month. Approximately 50% of patients in HeadPoST begun their head positioning in the emergency department. To alleviate this, subjects positioned in the emergency department were accepted into the study, resulting in a larger and more diverse population of the included disease group. Strong inter-departmental collaboration was required between wards and emergency departments to effectively manage this challenge.

The study protocol also allowed nurses to move patients and place them out of position for 30 mins, three times within 24 hours; then reverted back to the position they were in based on the poster above the patient's bed-head. This practical solution in the study design allowed for day to day activities in the ward to still be completed as they normally would.

The team on-sites were provided with extensive training to familiarise themselves with the CRT process. The study team and sites were provided with many training materials and events, such as multiple Investigator meetings, videos, face-to-face meetings with study team, and interaction with local leaders or champions. Feedback groups were also created from nurses and clinicians so that gaps in training were identified and actioned.

CONCLUSION

CRTS are increasingly being utilised in health services and primary care research. Although the design is quite novel, pragmatic solutions in the study design and study conduct process allowed site personnel to implement the study successfully. As CRTs are often large trials in practical settings, such easy-to-implement solutions are key. The posters placed above the patient's head in HeadPost is an example of simple, yet effective method that made the crossover process seamless.

About George Clinical: As a leading Asia Pacific CRO, George Clinical offers full clinical research services at a global scale. George Clinical works with top-tier and mid-sized pharmaceutical and medical technology companies in the conduct of mid and late phase trials of innovative drugs and devices.

A PROMISING HUB FOR CLINICAL RESEARCH

When you talk about medical drugs, consumers tend to fixate on their effectiveness and price. Rarely do they consider the long drawn out process that any new drug has to meet before making the journey from the laboratory to the pharmacies or hospitals.

But the field of clinical research, which involves the discovery of new drugs, medical devices or protocols, has a major impact on healthcare and the economy. There is a constant demand to address unmet medical needs in numerous diseases including diabetes, cardiovascular and cancer.

The development of a new drug is a 10- to 15-year process and its research and development (R&D) comes with numerous downstream and upstream economic activities.

Investments in such R&Ds are huge; pharmaceutical giant Novo Nordisk, for example, invests 15% of its sales revenue in R&D.

According to its General Manager for Malaysia, Singapore and Brunei, Noha Shawky, in 2013 the company invested US$2.1 billion in clinical trials for diabetes.

Dr. Akhmal Yusof,
CEO of Clinical Research Malaysia (CRM)

The global clinical trial industry is worth US$51 billion a year and in the last five years, clinical research has moved from developed countries in the West to the East – due to delay approvals and as well as rising costs and the procurement of subjects. For drug companies, these delays are costly as the life of a patent starts at the point of discovery of a drug and any delay in getting it to the market can push companies back by up to US$10 million per day.

Fewer hurdles in Asian countries like China, India and Southeast Asia has seen this industry growing at the rate of 30% year on year in this part of the world, said PEMANDU's Director of Healthcare NKEA, Fabian Bigar.

According to the Chief Executive Officer of Clinical Research Malaysia (CRM) Dr Akhmal Yusof, the pharmaceutical industry considers Malaysia as a potential hub for Industry-Sponsored Research (ISR), with the ability to deliver speed, quality and reliability.

Malaysia offers an excellent environment for clinical research with a sizeable pool of expert healthcare and research professionals conversant in English; genetic diversity through multi-ethnic population; and an extensive network of hospitals and clinics (government and private), which is among the best in the region. A consistent timeline for approval – typically about six to eight weeks for approval process – is extremely important, said Dr Akhmal.

Shawky, Bigar and Dr Akhmal were speaking at the Economic Transformation Programme Healthcare Link Event: Taking Industry–Sponsored Research to The Next Level: Is Malaysia Ready? held in Kuala Lumpur on Nov 16.

Malaysia has more than 80 ISR trial sites, which have been approved by the Ministry of Health (MOH), in conjunction with public and private hospitals as well as university hospitals. Trial cost per patients is at a competitive rate when compared with Singapore, Taiwan, South Korea and Japan.

ISR is not limited to research on pharmaceutical and medical devices; it includes novel hypothesis related to medicine, medical devices and clinical practices, with the objective of seeking clinical improvements for the management of diseases.

Despite some negativity surrounding ISR, the benefits to local industry are numerous, especially in the areas of technology transfer.

ISR exposes local investigators and research teams to the proper procedures for conducting a study in compliance with Good Clinical Practices. These include writing a clinical protocol, collecting empirical data and documentation procedures when reporting clinical case studies, explained Dr Akhmal. He added that this knowledge is not taught in classrooms and is crucial to ensure good practice and quality of local research work.

All this would go towards the development of the local pharma and medical device industry, as well as increasing local R&D capacity to allow Malaysia to tap into our huge natural bio-diversity. For the patients, ISR provides access to new life-saving drugs and medical devices.

"Currently, there are 869 new and ongoing ISRs, which have brought in more than RM118 million in investments and created 562 skilled jobs," he said. CRM's 2020 target is to raise the number of ISRs to 1,000, garnering a GNI of RM578 million and creating 1,000 high-skilled jobs.

CRM was established in 2012 to position Malaysia as a preferred global destination for ISR. The non-profit organisation, which is wholly-owned by MOH, acts as a facilitator and enabler for both the pharma industry and medical fraternity by pushing for the development of an efficient eco-system to increase the number of ISRs in the country.

"Our efforts also include creating public and industry awareness on clinical research and developing a pool of capable investigators, support staff and trial sites for high-quality ISR trials."

by Dr. Akhmal Yusof

Currently, Malaysia comes third in ASEAN after Thailand and Singapore in the number of industry-related clinical research, said Dr Akhmal.

SPONSORS AND CONTRACT RESEARCH ORGANIZATIONS (CROs) IN MALAYSIA

Sponsors

- Abbvie Sdn Bhd
- AstraZeneca Sdn Bhd
- Bayer Co. (M) Sdn Bhd
- Boehringer Ingelheim (M) Sdn Bhd
- CCM Pharmaceuticals Division
- Clinipace Worldwide
- Eisai (M) Sdn Bhd
- Eli Lilly (M) Sdn Bhd
- Janssen-Cilag
- Janssen
- GlaxoSmithKline Pharmaceutical Sdn Bhd
- Kotra Pharma (M) Sdn Bhd
- Merck Sharp & Dohme (M) Sdn Bhd
- Novartis Corporation (M) Sdn Bhd
- Novo Nordisk Pharma (M) Sdn Bhd
- Pfizer (M) Sdn Bhd
- Pharmanet Pte Ltd
- Roche (M) Sdn Bhd
- Sanofi Aventis (M) Sdn Bhd
- Takeda Malaysia Sdn Bhd
- Zuellig Pharma Sdn Bhd

Contract Research Organizations (CROs)

- Covance Services (M) Sdn Bhd
- EPS Global Research Pte Ltd
- ICON (M) Sdn Bhd
- INC Research
- IndiPharm(M) Sdn Bhd
- Info Kinetics Sdn Bhd
- inVentiv Health
- Klinsel Sdn Bhd
- MYXMO Sdn Bhd
- Novotech Clinical Research (M) Sdn Bhd
- PAREXEL International (Malaysia) Sdn Bhd
- PPD Development (S) Pte Ltd (Malaysia Branch)
- Questra Clinical Research Sdn Bhd
- Quintiles (M) Sdn Bhd
- SIRO Clinical Research Services (M) Sdn Bhd
- George Clinical Asia Pacific
- Veras Research Sdn Bhd

2nd International Conference on Phase 1 and Early Phase Clinical Trials

New Drug Research for Tomorrow – in Asia and Worldwide
21 – 22 November 2015, Hong Kong

The 2nd International Conference on Phase 1 and Early Phase Clinical Trials (ICPOEP 2015) was successfully held on 20 – 21 November 2015 at the Hyatt Regency, Tsim Sha Tsui, Hong Kong. This year's conference organized by the Li Ka Shing Faculty of Medicine, the University of Hong Kong, attracted over 340 delegates from five continents and 20 countries. It featured well-established medical and clinical research experts from Canada, China, Denmark, Hong Kong, Singapore, Taiwan, the UK and USA.

Aligned with the theme of "New Drug Research for Tomorrow – In Asia and Worldwide", 18 distinguished speakers showcased a wide variety of presentation topics from pre-clinical research, clinical research and drug development in the pharmaceutical industry. The panel discussions and Q&A sessions during the one and a half-day conference attracted active discussions among speakers, session chairs, panelists and delegates.

The opening ceremony was officiated by Dr. Wing-man Ko who is the secretary for Food and Health of Hong Kong SAR Government, Hong Kong, China. Malaysian delegates who participated in this conference were from the National Pharmaceutical Control Bureau (NPCB), Clinical Research Centre (CRC) and Clinical Research Malaysia (CRM). Through the experts' sharing, it is clear that phase 1 and early phase clinical trials are seeing a bloom in the Asia-Pacific region, and this region will definitely play a more important role in early development of new drugs on a global basis.

Opening ceremony by Dr Wing-man Ko, Secretary for Food and Health of Hong Kong SAR Government, Hong Kong, China

The Malaysian delegates at the ICPOEP 2015

CRM IN PHOTOS - HIGHLIGHTED ACTIVITIES IN 2015

Network of Ethical Review Committees in Malaysia (NERCIM), Kuala Lumpur (28th October 2015)

3rd Sabah Medical Research & Scientific Conference, Likas (15th–17th October 2015)

Sungai Buloh Hospital Research Day 2015, Selangor (18th–19th November 2015)

Pahang State Research Day 2015, Kuantan (17th November 2015)

National Hematology Update 2015, HTAR Klang (30th–31st October 2015)

Network of Ethical Review Committees in Malaysia (NERCIM), Kuala Lumpur (28th October 2015)

7th Sarawak State Health Department Research Day, Kuching (29th–30th September 2015)

Wilayah Persekutuan Kuala Lumpur and Putrajaya State Research Day (6th–8th October 2015)

2015 MOS Annual Scientific Meeting, Kuala Lumpur (17th–18th October 2015)

3rd Sabah Medical Research & Scientific Conference, Likas (15th–17th October 2015)

30th Anniversary of HTAR & Selangor Research Day 2015, Klang (29th October 2015)

PEMANDU Healthcare LINK - Taking ISR to the Next Level - Is Malaysia Ready, Kuala Lumpur (16th November 2015)

INDUSTRY NEWS

FDA Approves Two New Insulin Treatments for Diabetes Mellitus: Tresiba and Ryzodeg 70/30

http://www.themrs2000.com/uploads/1/6/2/3/1623943/3130254.jpg

The U.S. Food and Drug Administration today approved Tresiba (insulin degludec injection) and Ryzodeg 70/30 (insulin degludec/insulin aspart injection) to improve blood sugar (glucose) control in adults with diabetes mellitus. Tresiba and Ryzodeg should not be used in those who have increased ketones in their blood or urine (diabetic ketoacidosis). Patients or caregivers should monitor blood glucose in all patients treated with insulin. Insulin regimens should be modified cautiously and only under medical supervision. Tresiba and Ryzodeg may cause low blood sugar (hypoglycemia), which can be life-threatening. Patients should be monitored more closely with changes to insulin dosage, co-administration of other glucose-lowering medications, meal pattern, physical activity, and in patients with renal impairment or hepatic impairment or hypoglycemia unawareness. Tresiba and Ryzodeg are manufactured by Novo Nordisk in Plainsboro, New Jersey.

Merck and Pfizer Announce Initiation of Phase III First-Line Trial of Avelumab in Patients with Recurrent or Stage IV Non-Small Cell Lung Cancer

http://www.thepharmaletter.com/media/image/pfizer-merckbig.jpg

Darmstadt, Germany, November 4, 2015 - Merck KGaA and Pfizer today announced the initiation of an international Phase III study of the investigational cancer immunotherapy avelumab* in a treatment naïve advanced NSCLC setting. The study, JAVELIN Lung 100, is designed to assess the safety and efficacy of avelumab compared with platinum-based doublet chemotherapy, in patients with late-stage NSCLC who have not previously received any treatment for their systemic lung cancer. Avelumab (previously known as MSB0010718C) is an investigational fully human anti-PD-L1 IgG1 monoclonal antibody that potentially uses the body's own immune system to fight cancer.

Sanofi and Lexicon Pharmaceuticals to Collaborate on Sotagliflozin, an Investigational New Oral Medicine for People With Diabetes

http://yourstory.com//wp-content/uploads/2012/11/enterprise-collaboration.jpg

PARIS and THE WOODLANDS, Texas, Nov. 6, 2015 - Sanofi and Lexicon Pharmaceuticals Inc. announced today that they have entered into a collaboration and license agreement for the development and commercialization of sotagliflozin, an investigational new oral dual inhibitor of sodium-glucose cotransporters 1 and 2 (SGLT-1 and SGLT-2), which could be a potential treatment option for people with diabetes. The investigational agent described above is currently under clinical development and its safety and efficacy have not been evaluated by any regulatory authority.

Apricus Biosciences Completes Enrollment in Phase 2b Clinical Trial for Fispemifene in Men with Symptomatic Secondary Hypogonadism

https://upload.wikimedia.org/wikipedia/en/thumb/2/29/Apricus_Logo.jpg/210px-Apricus_Logo.jpg

SAN DIEGO, Oct. 28, 2015 - Apricus Biosciences, Inc., a biopharmaceutical company advancing innovative medicines in urology and rheumatology, today announced completion of enrollment in the company's Phase 2b clinical trial to evaluate its novel product candidate, fispemifene, a selective estrogen receptor modulator ("SERM"), for the treatment of symptomatic male secondary hypogonadism also known as "low testosterone." The study enrolled 161 patients across 15 sites in the United States. Consistent with previous guidance, Apricus remains on track to report top-line Phase 2b data during the first quarter of 2016.

LATEST FINDINGS & DISCOVERIES IN CLINICAL RESEARCH

Metformin does not improve glycemic control for overweight teens with type 1 diabetes

In a randomized trial that included overweight and obese adolescents with type 1 diabetes, the addition of metformin to insulin did not improve glycemic control after six months, report researchers. The researchers found that despite a small decrease in HbA1c (glycated hemoglobin; used to identify the average plasma glucose concentration over prolonged periods) favoring the metformin group at 13 weeks, average HbA1c levels increased by approximately 0.2 percent from baseline values of 8.8 percent in each treatment group at 26 weeks. There also were no statistically or clinically significant differences from baseline to 26 weeks in continuous glucose monitoring between treatment groups. The researchers add that it does not seem likely that different glycemic control results would have been achieved with a longer treatment period.

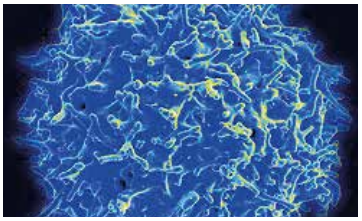
Source: The JAMA Network Journals (December 1, 2015)

Plant hormone may play a vital role in blood sugar control, diabetes management

A treatment for managing blood sugar levels might be as close as the local health food store, suggests a new research report published in the December 2015 issue of The FASEB Journal. Specifically scientists from Italy have found that when the plant and mammal hormone, abscisic acid, is taken in low doses, glycemia in both rats and humans is reduced. This suggests that by reducing the chronic stimulation by hyperglycemia of β-cells to the release of insulin, chronic low-dose abscisic acid administration may prolong the survival and function of these cells.

Source: Federation of American Societies for Experimental Biology (December 1, 2015)

Immunotherapy for type 1diabetes deemed safe in first US trial



Patients experienced no serious adverse reactions after receiving infusions of as many as 2.6 billion cells that had been specially selected to protect the body's ability to produce insulin, report scientists and physicians at the end of a trial focused on a new type 1 diabetes immunotherapy approach.

Source: University of California – San Francisco (November 25, 2015)

An easy pill to swallow

Amrita Banerjee holding the enteric capsule with insulin-loaded patches. Credit: Sonia Fernandez

An insulin pill being developed by researchers at UC Santa Barbara may in the near future give another blood sugar management option to those who suffer from diabetes. The novel drug delivery technology may also apply to a wide spectrum of other therapies. While oral medications to assist the body with insulin production have been around for a while, a pill that delivers insulin remains a highly sought goal of diabetes medicine. The main obstacle to its development has been getting the medication past the hostile proteolytic environment of the stomach and intestine without destroying the protein itself. In this case, the key is a combination of enteric-coated capsules and insulin-loaded mucoadhesive polymer patches that were optimized by Banerjee as part of her research. The new pill has demonstrated its ability to survive stomach acids with the protection of the enteric-coated capsule and deliver its payload to the small intestine. There, the capsule opens up to release the patches that adhere to the intestinal wall, preventing access of proteolytic enzymes to insulin and, with the aid of a permeation enhancer, depositing insulin that can pass through to the blood.

Source: University of California – Santa Barbara (November 18, 2015)

INSTITUTIONAL REVIEW BOARDS & TRIAL SITES IN MALAYSIA

12 Institutional Review Boards + 1 Centralised Ethics Committee

- Medical Research Ethics Committee (MREC)
- Joint Penang Independent Ethics Committee (JPEC)
- Medical Ethics Committee University Malaya Medical Centre (MECUMMC)
- Independent Ethics Committee Sime Darby Healthcare (IECSDH)
- Sunway Medical Centre Independent Research Ethics Committee (SREC)
- International Medical University (IMU) Joint Committee of the Research and Ethics Committee (IMUJC)
- National Heart Institute Ethics Committee
- IIUM Research Ethics Committee (IREC)
- Joint Ethics Committee School of Pharmaceutical Sciences, Universiti Sains Malaysia (USM) – Lam Wah Ee Hospital on Clinical Studies
- Ethics Research Committee Universiti Teknologi MARA (UiTM)
- Ethics Research Committee Universiti Putra Malaysia
- Ethics Research Committee Universiti Sains Malaysia
- Ethics Research Committee Universiti Kebangsaan Malaysia

MOHE Hospitals

- University Malaya Medical Centre
- Hospital Universiti Kebangsaan Malaysia
- Hospital Universiti Sains Malaysia

Private Hospitals

- Beacon International Specialist Centre
- Chinese Maternity Hospital
- Columbia Asia Medical Centre
- Gleneagles Medical Centre
- International Specialist Eye Centre (ISEC)
- Ipoh Specialist Hospital
- Island Hospital
- KPJ KL
- Lam Wah Ee Hospital
- Loh Guan Lye Specialist Centre
- Mahkota Medical Centre
- Metro Specialist Hospital
- Mount Miriam Cancer Hospital
- National Heart Centre (IJN)
- Nilai Medical Centre
- Normah Medical Specialist Hospital
- Pantai Hospital Ayer Keroh
- Pantai Hospital KL
- Pantai Hospital Penang
- Penang Adventist Hospital
- Prince Court Medical Centre
- Sabah Medical Centre
- Sime Darby Medical Centre
- Sunway Medical Centre
- Tun Hussein Onn National Eye Hospital

Phase I / BABE sites, Pre-clinical and GLP-certified laboratories in Malaysia

Phase I / BABE Sites

- Info Kinetics Sdn. Bhd.
- Cardiology Ward, Penang General Hospital
- Clinical Trial Complex (CTC), Advanced Medical &
- Dental Institute, Universiti Sains Malaysia
- Clinical Research Centre (CRC), Penang General Hospital
- Clinical Trial Unit, Clinical Research Centre, Seberang Jaya Hospital
- Clinical Research Ward, Ampang Hospital
- Bioequivalence Centre, Pharmacy-Hovid Research Sdn. Bhd.,
- School of Pharmaceutical Sciences, Universiti Sains Malaysia
- CRC Research Ward, Sarawak General Hospital Heart Centre
- University of Malaya Bioequivalence and Testing Centre (UBAT)
- Questra Bio-Clinical Research Centre

Pre-clinical Labs

- Cerca Insights Sdn Bhd
- Environmental Technology Research Centre (ETRC), Sirim Berhad
- Info Kinetics Sdn Bhd
- Institute for Medical Research
- IPharm Animal Research Facility (IPARF)
- Melaka Biotechnology Corporation

GLP Certified Labs

- Environmental Technology Research Centre
- Info Kinetics Sdn Bhd
- Melaka Biotechnology Corporation
- Non-clinical Research, Laboratory Animal Resource
- Unit, Medical Research Centre, Institute for Medical Research

Trial Sites in Malaysia

Public Hospitals / Health Clinics

- Hospital Ampang
- Hospital Bahagia Ulu Kinta
- Hospital Duchess of Kent
- Hospital Kajang
- Hospital Kuala Lumpur
- Hospital Melaka
- Hospital Mesra Bukit Padang
- Hospital Miri
- Hospital Permai
- Hospital Pakar Sultanah Fatimah
- Hospital Pulau Pinang
- Hospital Putrajaya
- Hospital Queen Elizabeth
- Hospital Queen Elizabeth II
- Hospital Raja Perempuan Zainab II
- Hospital Raja Permaisuri Bainun
- Hospital Seberang Jaya
- Hospital Selayang
- Hospital Sentosa
- Hospital Serdang
- Hospital Seri Manjung
- Hospital Sibu
- Hospital Sultan Abdul Halim
- Hospital Sultan Ismail
- Hospital Sultanah Aminah
- Hospital Sultanah Bahiyah
- Hospital Sultanah Nora Ismail
- Hospital Sultanah Nur Zahirah
- Hospital Sungai Buloh
- Hospital Taiping
- Hospital Tengku Ampuan Afzan
- Hospital Tengku Ampuan Rahimah
- Hospital Tuanku Ampuan Najihah
- Hospital Tuanku Fauziah
- Hospital Tuanku Jaafar
- Hospital Umum Sarawak
- Hospital Wanita dan Kanak Kanak Likas
- Institut Perubatan Respiratori (IPR)
- KK Ampangan
- KK Bandar Baru Air Itam
- KK Bandar Sungai Petani
- KK Cheras Baru
- KK Greentown
- KK Jaya Gading
- KK Jelapang
- KK Karak
- KK Lenggong
- KK Lukut
- KK Pasir Gudang
- KK Putrajaya
- KK Seremban 2
- KK Setapak
- KK Shah Alam Seksyen 7
- KK Simpang Kuala
- KK Tampin
- KK Tanglin
- Klinik Pergigian Gunung Rapat
- Klinik Pergigian Putrajaya
- Klink Pergigian Cahaya Suria
- Pusat Darah Negara (PDN)
- Pusat Jantung Hospital Umum Sarawak

EVENTS IN 2016

2016 National & International Events

- **BioMalaysia Asia Pacific Bioeconomy 2016**
  31st May – 2nd June, Kuala Lumpur
- **BioPharma Asia Convention 2016**
  22nd – 24th March, Singapore
- **28th Annual EuroMeeting**
  6th – 8th April 2016, Hamburg, Germany
- **DIA 2016 52nd Annual Meeting**
  26th – 30th June 2016, Philadelphia
- **CPhI Worldwide**
  4th – 6th October 2016, Barcelona, Spain
- **5th Clinical Trials Innovation Programme**
  27th – 28th June 2016, Hamburg, Germany
- **8th Annual Asian Oncology Summit**
  3rd – 6th March 2016, Kyoto, Japan
- **6th International Conference and Exhibition on Biologics and Biosimilars**
  19th – 21st October 2016, Houston, USA
- **10th National Conference for Clinical Research**
  27th – 29th July 2016, Kuala Lumpur
- **NHAM Annual Scientific Meeting 2016**
  8th – 10th April 2016, Kuala Lumpur
- **APHM International Healthcare Conference and Exhibition**
  1st – 3rd June 2016, Kuala Lumpur
- **11th Asia-Pacific Oncologists Annual Meeting**
  17th – 19th October, Kuala Lumpur
- **ICPPM 2016: 18th International Conference on Pharmacology and Pharmaceutical Medicine**
  11th – 12th February 2016, Kuala Lumpur
- **8th "Diabetes Complications" Conference & Grand Rounds**
  6th – 8th May 2016, Kuala Lumpur
- **Endoscopy 2016**
  8th – 10th April 2016, Kuala Lumpur
- **23rd Perinatal Society of Malaysia Regional Congress**
  21st – 24th April 2016
- **32nd Annual Congress of the Malaysian Society of Nephrology**
  29th – 1st May 2016, Johor
- **College of Surgeons Annual Scientific Meeting 2016**
  13th – 15th May 2016, Kuala Lumpur
- **13th Annual Scientific Meeting of the Malaysian Society of Hypertension**
  15th – 17th January 2016, Kuala Lumpur

MINISTRY OF HEALTH MALAYSIA

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