By Clinical Research Malaysia

CRM bulletin

of Clinical Research and Therapy

ISSUE 16

Tackling Infectious Disease

RESEARCH PERSONALITY
Dato' Dr Mahiran Mustafa

SPECIAL COVERAGE
Pharma Boardroom: Dr Akhmal - CRM

FEATURED SITE
Hospital Raja Perempuan Zainab II

CRM
CLINICAL RESEARCH MALAYSIA
Your Global Solutions in One Nation

We have moved!

Clinical Research Malaysia has now moved to our new office to provide better service for clinical research. We now operate from:

D-26-06, Menara Suezcap 1,
KL Gateway, No. 2 Jalan Kerinchi,
Gerbang Kerinchi Lestari,
59200 Kuala Lumpur.

We could be contacted through:

Phone number: **+603 7931 5566**
Facsimile number: **+603 7931 9940**

Our individual team member emails remain unchanged and if you need further clarification you could write to **contact@clinicalresearch.my**

We appreciate your continuous support and look forward to continuing growing clinical research in Malaysia together from the new office.

FROM THE CEO's DESK

At CRM, our vision is to establish Malaysia as a preferred destination for industry-sponsored research (ISR). We focus our work to meet the expectations of the clinical research industry as well as our investigators to provide the best for the people. As we approach the end of the year, 2018 has been the perfect embodiment of our efforts to reach that vision..

For the year 2018, we have seen that the number of studies for industry-sponsored research has been more than Bioavailability/Bioequivalence studies (BA/BE), at 79% and 21% respectively. Unlike previous years where BA/BE studies are always dominant, the trend is now changing, and we are seeing more industry-sponsored research being carried out here in Malaysia. Meaningful research provides intangible benefits to doctors and patients, especially in terms of treatment options. This change in trend is also reflective of the interest and traction the country is gaining from the clinical research industry worldwide. The industry is now beginning to see how Malaysia can be a fruitful investment for their clinical research efforts.

All of these would not be possible without the excellent work by our Principal Investigators (PI), Study Coordinators (SCs) and Clinical Research Centres (CRC). As an example, Dr. Toh Teck Hock and his clinical research team from Hospital Sibu in Sarawak were recognized as the world's top 5 recruiter in the global RESPIRE RSV (Respiratory Syncytial Virus) study whereas Dr. Rohan Malek and his clinical research team at Hospital Selayang was the top recruiter for the ELIGANT study, which is a phase IV interventional study in prostate cancer patients in Asia. These international accomplishments are a testament to how far the clinical research landscape in Malaysia have grown and developed.

Finally, as a great ending to our arguably most productive year, I am proud to announce that CRM has successfully achieved the accreditation for ISO 9001:2015. CRM is the first clinical research organization in Malaysia to have achieved this accreditation and there is no one else more deserved to be credited with this achievement other than our people in CRM. They have worked tirelessly around the clock, providing training and getting trained, and keeping abreast with the stringent ISO requirements. We hope with this accreditation our stakeholders and industry players are now convinced that our services are of the highest standards. Here is to a more fruitful year ahead for everyone!

Dr. Akhmal Yusof
CEO, Clinical Research Malaysia

Contents

Nurturing New Talents in ISR: Gastroenterology

KEDAH, 22 November – A Talk Series on Nurturing New Talents in Industry Sponsored Research focusing on gastroenterology was held at Hospital Sultanah Bahiyah (HSB) with the aim to develop and grow the pool of investigators in clinical research. The half-day event was well-attended by 50 participants comprising of medical officers, specialists and pharmacists. Among the topics covered include the basics of clinical research, best practices and expectations towards investigators in clinical trials. Datuk Dr. Muhammad Radzi Abu Hassan (Consultant Physician and Gastroenterologist, HSB) and Mr. Vishnu Chandra (Senior Manager, Clinical Operations, PAREXEL) were among the speakers on that day.

Hospital Sibu Among the Top 5 Global Recruiters for RESPIRE RSV Study

SIBU, June – Dr. Toh Teck Hock and his clinical research team has set another milestone for Hospital Sibu, Sarawak for the Phase IIb RESPIRE study recently. Dr. Toh and team were the top 5 global recruiter for this study that aims to treat respiratory syncytial virus (RSV) infections in infants younger than two years of age.

"Although Sibu has a few queries (which is normal), our Study Coordinators (SC) were fast to resolve those queries. To me it shows the "Quality" work our SC has done, besides also having a good Co-I" said Dr. Toh, who is also the Head of Clinical Research Centre at Hospital Sibu.

RSV is the most common cause of lower respiratory tract infections and the leading viral cause of severe lower respiratory tract disease in infants and young children worldwide. It is the primary cause of infant hospitalisation and virus-associated deaths in infants, with estimated global annual infection of 33 million infants and young children and the resulting hospitalisation of 3-4 million. RSV is associated with an estimated 3,000-8,500 deaths in infants <2 years globally per year, and it has been linked to an increased risk of asthma development later in life. Current treatment of RSV infections is primarily focused on symptomatic relief, hence the need for an effective and specific anti-RSV therapeutic.

CRM would like to congratulate Dr. Toh and his team in Hospital Sibu for this great achievement!

Hospital Selayang Top Recruiter for ELIGANT study

Dr. Rohan Malek and his clinical research team at Hospital Selayang was the top recruiter for the ELIGANT study, a phase IV interventional safety study of ELIGARD® in prostate cancer patients in Asia. First patient in was 15 days after Site Initiation Visit (SIV) and a total of 12 patients were recruited (patient enrolment target was 9), thus achieving 133% of the patient enrolment target. Overall, the recruitment was completed 1.5 months ahead of the timeline. CRM would like to congratulate Dr. Rohan and his team for this achievement!

R-L: Mr.Toh Charng Chee, Dato' Dr. (Mr) Rohan Malek , Sr.Fahizah (SC) ,Siti Nurliana(SC), Hasidah & Dr. Iliati Ibrahim.

Malaysia Joining in The Race for World Health Innovation in Doha

QATAR, 14 November – Dr Khairul Faizi Khalid, Head of Business Development of Clinical Research Malaysia (CRM) visited Qatar in Doha for the World Innovation Summit for Health 2018 which took place on the 13 – 14th November 2018. This summit saw over 2000 healthcare experts, innovators, entrepreneurs, policy makers, and ministers from over 100 countries gathered together for one common goal: working towards a healthier world. CRM utilized this platform to exhibit Malaysia's clinical research capability to the global community and at the same time displayed Malaysia's contribution to the innovation taking place in the healthcare world.

Stakeholders & Industry Players Gather Again for Industry Dialogue 2

KUALA LUMPUR, 17th October – For the second time in this year, the CRM bi-annual Industry Dialogue has once again provided an avenue for stakeholders and industry players to come together and discuss important issues regarding conducting clinical trials in Malaysia. Stakeholders from the likes of National Pharmaceutical Regulatory Agency (NPRA) and Medical & Research Ethics Committee (MREC) were present to provide relevant updates to the industry and helped to address any pressing issues that surfaced. The dialogue saw over 60 industry players attending to share opinions and voice out concerns.

Exhibiting Malaysia Internationally at ESMO

MUNICH, 23 October – For this year again, the Clinical Research Malaysia (CRM) team went to Munich in Germany to exhibit at the annual European Society for Medical Oncology (ESMO). Held under the tagline "Securing access to optimal cancer care", the ESMO 2018 Congress took place between 19 and 23 October and was attended by delegates from over 150 countries. The CRM team was led by CRM CEO, Dr. Akhmal Yusof and Head of Business Development, Dr. Khairul Faizi Khalid, and accompanied by CRM Associate Regional Manager, Ms. Nor Hafiza Johari and Feasibility Specialist, Dr. Noorzaihan Mat Radi.

Discussing Ethics Review in NERCIM 2018/2

KUALA LUMPUR, 22 October – The Network of Ethics Review Committees in Malaysia (NERCIM) gathered again for their second meeting in this year at Pullman Bangsar, Kuala Lumpur. Led by the Chairperson of the Medical & Research Ethics Committee (MREC), Dr. Salina binti Abdul Aziz, this bi-annual meeting discussed pertinent issues revolving clinical research ethics in Malaysia. This meeting also saw Mr Nicholas Leow Chun Wei, a representative from the National Pharmaceutical Regulatory Authority (NPRA) attending to offer his expertise on the subject matter. This meeting was co-organised by Clinical Research Malaysia (CRM) and the Medical Research Ethics Committee (MREC) and attended by various Institutional Review Boards (IRB) representatives from all over Malaysia.

CRM Forms Closer Ties with its Japanese Counterparts in Clinical Research

TOKYO, 5 – 7 November – Clinical Research Malaysia (CRM) held a half-day seminar that targets Japanese pharmaceutical and medical device companies interested in conducting clinical trials in the Asian region. This is the first time for CRM to deliver a clinical trial seminar focusing on its home country in Japan. 22 Japanese pharmaceutical companies attended the seminar that was held at The Strings by InterContinental in Tokyo. Speaking at the seminar was Datuk Dr. Shahnaz Murad (Deputy-Director of Health (Research & Technical Support), Ministry of Health Malaysia), Dr. Yoko Aoi (Principal Planning and Coordination Officer, Office of International Cooperation, PMDA, Japan) and Professor Dr. S. Fadilah (Head of Cell Therapy Centre, UKM Medical Centre). CRM provided a detailed insight into Malaysia's experience and capabilities in various types of industry-sponsored clinical trials.

L-R: Ms. Audrey Ooi, Dr. Khairul Faizi, Professor Dr. S. Fadilah, Dr. Akhmal Yusof, Datuk Dr. Shahnaz Murad, Dr. Yoshikazu Hayashi, Dr. Nobusama Nakashima, Dr. Junko Sato, Ms Akiko Ogata, Dr. Eriko Fukuda

Datuk Dr. Shahnaz Murad and the CRM team had a series of business networking meetings with the Pharmaceutical and Medical Device Authority, ICVS Tokyo Clinic, Japan Clinical Oncology Group, Ministry of Health, Labour and Welfare (MHLW), Osaka University Hospital and Kobe Eye Centre. The meetings were aimed at seeking further collaboration in several areas of clinical trials. Among the prominent stakeholders that the Malaysian delegation met was Dr. Suzuki Yasuhiro (Vice Minister of MHLW), Prof Dr. Sawa Yoshiki (Professor at Department of Cardiovascular Surgery, Osaka University), Prof Masayo Takahashi (Project Leader at RIKEN Laboratory for Retinal Regeneration), Dr. Nobumasa Nakashima (Senior Director for Internation Programs, PMDA), Dr. Kenichi Nakamura (Director of JCOG and Division Chief) and Dr. Toshirou Nishida (Director of National Cancer Center Hospital).

CRM's counterpart in Japan, intellim Corporation, which is the fastest growing independent CRO in Japan, provided support to CRM in coordinating the seminar and meetings. CRM signed a Memorandum of Understanding with intellim Corporation in March 2018 to foster strategic partnership in terms of providing support and valuable resources to complement the needs of both county in terms of business development, clinical trials operations and trainings.

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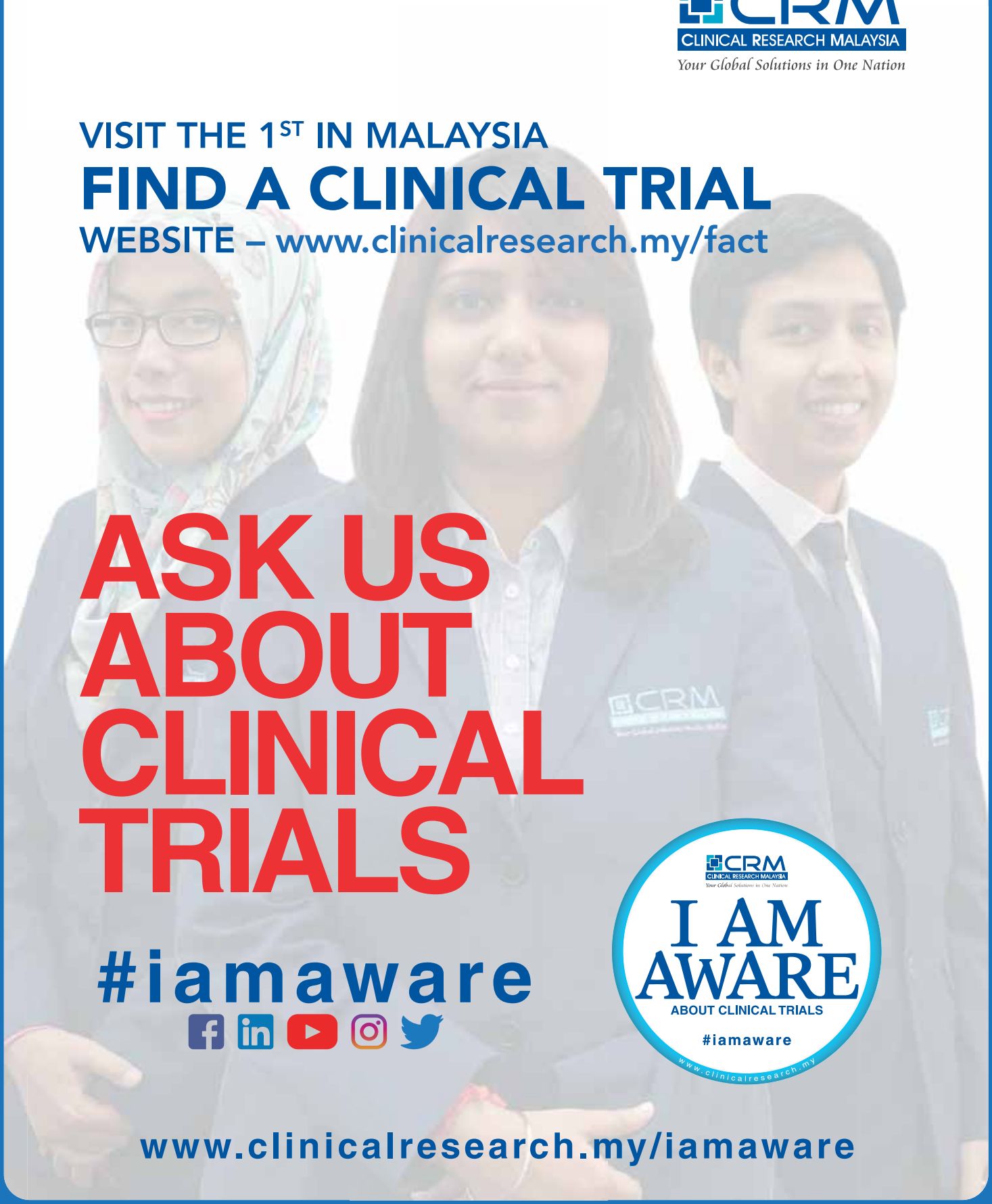
WEBSITE – www.clinicalresearch.my/fact



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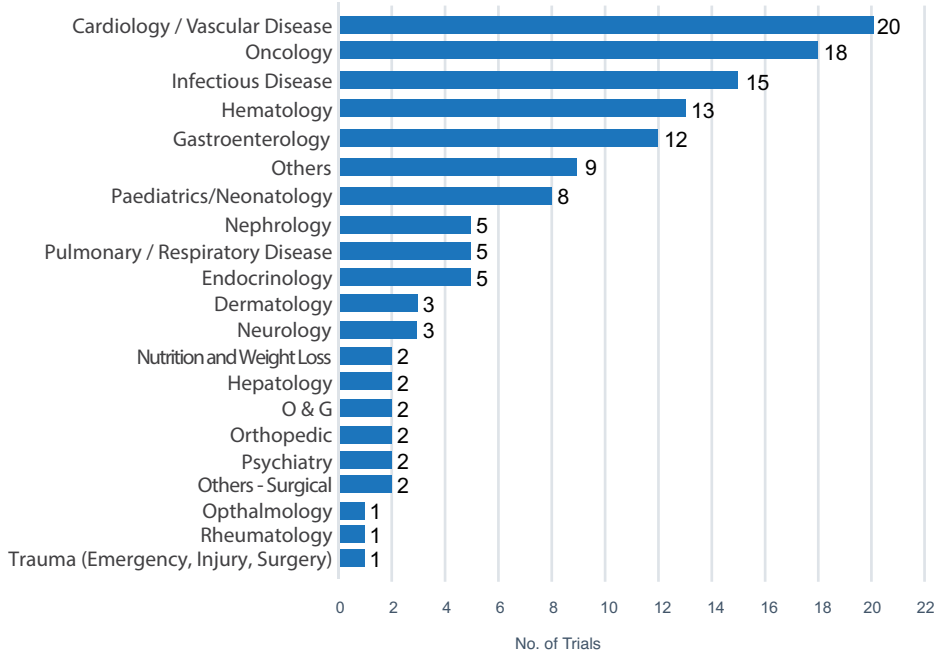
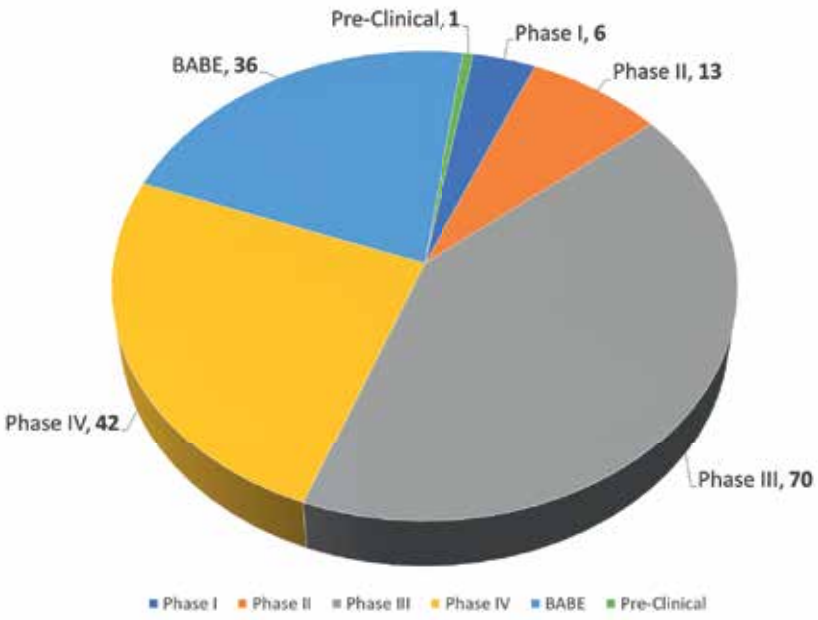
Malaysia's 2018 ISR Statistics



ISR Statistics According to Therapeutic Area in 2018

The top 3 therapeutic areas of ISR conducted in 2018 are cardiology/vascular diseases, oncology and infectious diseases.

In 2018, 37 Bioequivalence studies were conducted, bringing in a total of 168 ISRs in that year.

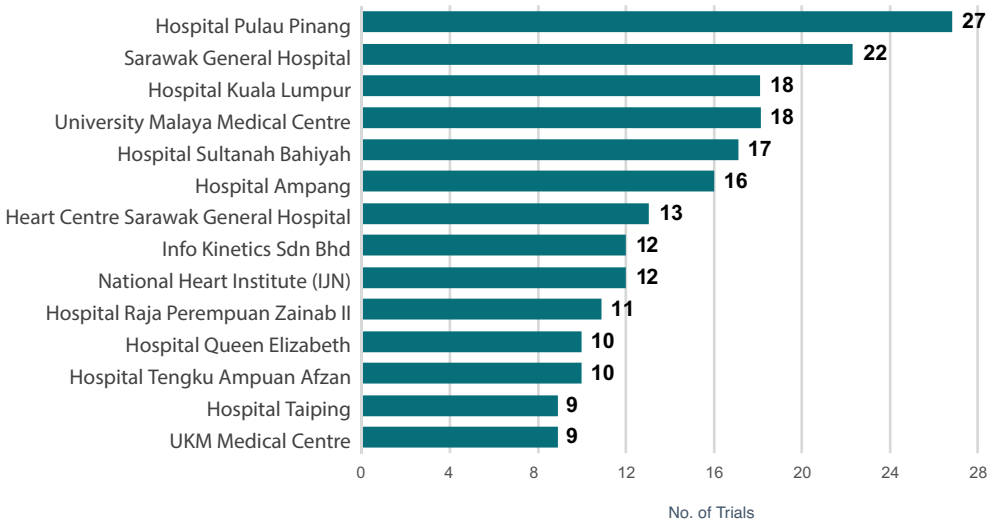


Clasification of ISR in 2018

Phase III studies form the largest type of ISRs in 2018, followed by bioequivalence studies and observational/registry studies.

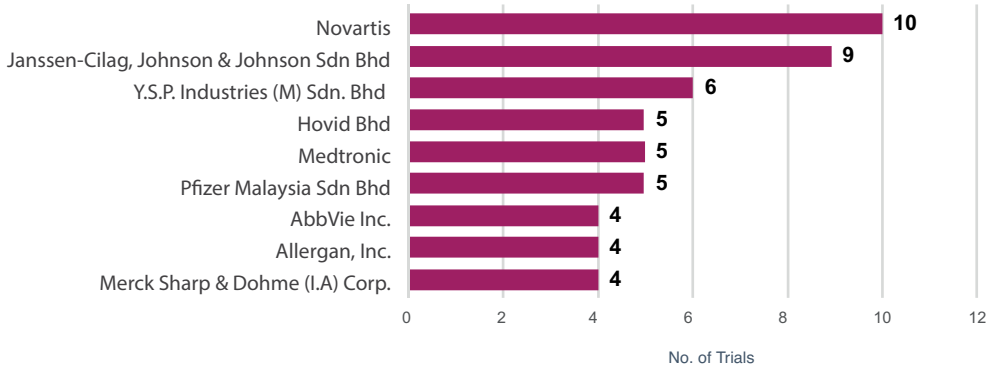
Top ISR Sites in 2018

Among the top three ISR sites in 2018 are Pulau Pinang Hospital, Sarawak General Hospital and Kuala Lumpur Hospital. UMMC is the top MOHE site while Pantai Hospital Kuala Lumpur is the top private hospital with ISRs in 2018.



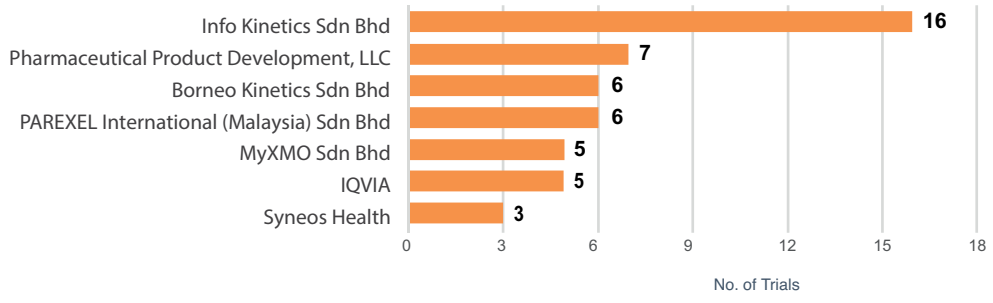
Top 5 Sponsors with the Most ISR in 2018

Novartis, Janssen-Cilag and Y.S.P. Industries were the top 3 sponsors in Malaysia in 2018.



Top 5 CROs with the Most ISR in 2018

Info Kinetics, PPD, Borneo Kinetics and PAREXEL were the top 3 contract research organizations in Malaysia performing ISRs in 2018. Bioequivalence studies made up the majority of ISRs conducted by Info Kinetics, a locally based CRO located in Penang.



PHARMA BOARDROOM:
Akhmal Yusof – CEO, Clinical Research Malaysia (CRM)

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Dr Akhmal Yusof, CEO of CRM sheds light on the capacity for all stages of clinical research in Malaysia. He discusses the importance of human resources for the country's research future and explains what makes Malaysia such a worthwhile location to invest in international clinical research.

> **"If we consider the level of sponsored clinical research per capita, Taiwan and Hong Kong are conducting three to four times the level of research as Malaysia, so we have significant scope for growth"**
>
> **– Dr. Akhmal Yusof**

Could you give our international readers an introduction to the scope of CRM's operations?

CRM was created by the Ministry of Health of Malaysia in 2012 to increase the level of sponsored clinical research conducted in Malaysia. If we consider the level of sponsored clinical research per capita, Taiwan and Hong Kong are conducting three to four times the level of research as Malaysia, so we have significant scope for growth.

We have five key strategic areas of operations. Firstly, we familiarise our doctors with conducting studies and ensure they are GCP (Good Clinical Practice) accredited. Secondly, we assist research sites in fulfilling all necessary requirements of the prospective sponsored clinical research. Thirdly, we collaborate closely with clinical research stakeholders, which includes the sponsors, regulatory authorities, ethics committees and national agencies. While under the Ministry of Health, we also work with players from across the universities and private sectors including pharmaceutical/research industry. This enables us to pool ideas and find the best way to advance. It is also important to know issues that other stakeholders face, for example the challenges pharma is encountering when trying to conduct research in Malaysia. Next, we aim to raise the public awareness of CRM and specifically clinical research. Thus, we are very active on all social media platforms as well as in national & international conferences. Finally, we invest in human capital to create careers in clinical research.

Our aim is for all our study coordinators: doctors, nurses, and bio science graduates, to have the ability to build a career in clinical research. We do not want them to be coerced into other fields due to economic reasons. We want them to stay in the areas where they are passionate and pursue their interests further. We have grown by over 150 percent since 2012. We began with a team of around 75 people, now we have 165 employees, and will reach 179 by the end of the year. This is because there are now 850 new and ongoing researches which need study coordinators in multiple sites. My team is undertaking the site resource management for these researches over 500 sites.

What is it about Malaysia that makes it a good place to host clinical researches?

We have a population of 32 million which represents a third of the world's genomics. To understand how pharmacokinetics works in these populations, a research will require an adequate pool of patients, which Malaysia can provide. When they are looking at the effects of certain conditions on minority groups, it is thus very beneficial to conduct such studies in Malaysia. Moreover, Kuala Lumpur is home to the biggest hospital in Southeast Asia – Hospital Kuala Lumpur. It has more than 2,000 beds and over 6,000 health care personnel work there. In Malaysia, there are several hospitals of a similar size. Hence, there is a huge pool of patients within a diverse range of therapeutic areas.

Secondly, we have a good command of English so there is no need for documents to be translated. This cuts bureaucracy and increases the accuracy of administration. Thirdly, the common diseases in Malaysia are the similar in the western populations.

Finally, we work very hard in maintaining timelines. The timeline to review clinical researches in the country has been reduced tremendously. The ethics review committee under the Ministry of Health now sits twice a month, helping us to complete the review of these study proposals at Ministry of Health sites within six to eight weeks. Moreover, reports have shown that the timeline could be cut further down to 31 days in the case of no issues. Considering reduced timelines in ethics and regulatory review, Malaysia is now one of the most efficient places in the region to conduct research.

How do you attract the stakeholders to bring the multi-national companies to Malaysia?

To attract the studies to Malaysia, we must be good at three things. Our first requirement is that we must maintainour short timelines. Secondly, we must be reliablein recruiting the number of

research patients required. The final point is the most significant as it touches upon the quality of the data garnered for research. Since we are aiming to prove safety and efficacy of new treatments, data must be quality-compliant and adhere to protocol. It is by maintaining that quality that we attract not only the largest MNCs but also the new upcoming biotech companies.

What is the potential at this time to create infrastructure for early stage clinical research in Malaysia?

Currently, Malaysia lacks exposure on the world stage for its involvement in early stage researches, as the number we conduct is still small. Thus, we are working with centres in Malaysia to develop their capacity for phase I or pre-clinical researches. This is part of the Ministry of Health's plan to develop early stage researches.

Indeed, all research centres, namely hospitals, are being equipped for early phase development. Standard operating procedures are currently being developed to fulfil regulatory requirements for site accreditation. CRM has provided resources to improve facilities and infrastructure at these sites. Finally, we have created a risk management system. We need to have good communication and manage risks well so that when things go wrong, we can manage the situation effectively.

In conjunction with this, we are ensuring that our researchers have the appropriate training to conduct early stage researches. We are sending medical professionals on scholarships to train in centres that have conducted a large number of early phase researches, for example Kings College London and the Christie, Manchester. Moreover, the country has formed a scientific review panel to support our ethics committee in performing scientific evaluation of phase I studies. Experts in the field of pharmacology, toxicology, and scientists having conducted phase I studies abroad are participating in the panel in the aim to review first-in-human studies, so that if a study is suggested, it is properly vetted to ensure that it can be conducted safely in Malaysia.

One of your mandates is to conduct feasibility studies in Malaysia. What are the main stumbling blocks that prevent some clinical researches from being brought to Malaysia?

One of the challenges is in meeting the recruitment target set. This we have noted is due to overpromising in number of targeted research patients at the initial stage due to limited information/ data source. Taking note of this, CRM has begun working closely with the Ministry of Health for access to the Malaysian Health Data Warehouse (MyHDW) to ensure a more accurate data representation in targeted recruitment number.

The other challenge is attracting patients to join clinical research. This is why we are running the "I Am AWARE" campaign nationwide which provides the public with a true view of clinical researches. There is a stereotype that clinical research is only an experimentation when it should be seen as a potential treatment for the patient.

We have heard from others in the industry that there is a worry of a brain drain in Malaysia. How do you overcome this to ensure that you recruit the best people?

The brain drain in Malaysia is a challenge that we face, and part of the solution will require changes to our government policy. From our perspective, we are invited by national talent management agency to speak with doctors abroad and present to them the opportunities that are available in Malaysia. In my view, clinical research is one of the areas which could encourage our Malaysian talents to return. We also invest heavily in training our staff so that they have the talent and skills to achieve great things if they cross over to international and local companies. A number of our former staff have moved on to Boston Scientific, Novo Nordisk, PPD, Johnson-Johnson, MSD and even organisations like DNDi. Consequently, the calibre of research team that we produce is of high standard.

Digitalization has become a key theme for the new Malaysian government. How do you see greater digitalization benefiting clinical researches?

Digitalization will be a positive step. Perhaps in the future the patient will no longer have to go to the doctor to partake in the research. For instance, there are companies that have medical devices that can be synchronised with smartphones, measuring heart beat and ECG which could be sent directly to the medical professional. Thus, studies could be conducted remotely, with patients only having to go to the hospital once, which would be considerably easier for them. Digitalization will also mean that there will be a wealth of data in terms of research: how the patient is improving in relation to standard therapy, and how the patient is faring against the new therapy.

What are the key priorities for CRM in the next four years?

We are in the final stages of ISO9001:2015 accreditation, currently completed internal audit. In November, we will begin the improvement plan, and by late November, the external auditing will begin. We are on track to obtain accreditation by the first quarter of 2019. Many of our personnel are located across Malaysia with only 30 people working in our headquarters. Thus, we need to have standard operating procedures which would ensure consistency on the quality of our studies across the country. Gaining recognition in international standards would strengthen our position as a globally trusted research organisation. This means that we may be moving towards consultancy, providing services to other nations around the region to conduct research. This is how we believe that we are able to develop new business opportunities.

Dato' Dr Mahiran Mustafa

Consultant for Infectious Disease and Physician at Hospital Raja Perempuan Zainab II
State Physician for Kelantan and Assistant for National Head of Infectious Disease, Ministry of Health

I started my career as a House Officer (HO) at Hospital Universiti Sains Malaysia (HUSM) after I graduated from the University Hospital of Wales, United Kingdom in 1987. Later, I joined a master program in Internal Medicine at HUSM and was subsequently qualified as a physician in the year 1993.

In 1993, I was posted at Hospital Raja Perempuan Zainab II (HRPZ II), Kota Bahru as a physician. Later in 2001-2003, I joined as a trainee in the field of Infectious Disease and was attached to Hospital Kuala Lumpur and Newcastle upon Tyne Hospital in the United Kingdom. During this training period, I did a lot of clinical audits and clinical studies and had successfully submitted for a poster publication in United Kingdom and Europe. In 2011, I did a short attachment at the Hospital of Infectious Control at Glasgow Hospital in Scotland.

Currently, I am actively involved as a coordinator for the Technical Working Group for National Antimicrobial Action Plan. I am also the Chairperson for Clinical Practice Guidelines: Management of Dengue Infection in Adults where we train health providers on dengue management. Apart from that, I work as a State Physician in Kelantan as well as a coordinator for my Hospital Infection and Antibiotic Control. I carry out many more tasks at the national level as a committee member and continue to serve as a consultant for Infectious Disease.

Can you tell us when and how did you first got involved in clinical research?

I started an interest in clinical research during my master's degree training at HUSM. After I qualified as a physician, I began involving in pharma-drug trials from 1997 and continue to actively involve as a supervisor for postgraduate Internal Medical candidates in their research projects.

When I was the Head of Medical Department in HRPZ II from 2011 till 2017, I realised that having a strong research team was our asset to participate in international clinical research and be recognised as a centre for clinical trials. I took this opportunity to start training my junior specialists and paramedics by sending them to GCP courses conducted by CRC. As the Head of Department (HOD), I kept encouraging specialists to participate as investigator and our goal at that time was that each specialist to conduct or participate in two clinical trials.

As for my team, we have completed at least 10 trials and currently another 4 trials have been approved and are due to start in December 2018 and January 2019.

Based on the number of trials and appraisal by sponsors, we are very proud that our department is recognised as one of the leaders in clinical trials at hospital or ministry level.

How has a clinical trial changed your practice and management of patient care?

Often, I use the experiences I have gained in clinical trials to improve my own way of practicing medicine during my clinical work. I have become even more particular in documenting clinical history and signs, more particular in providing options on treatments to patients and more respecting of their choices.

Clinical research helps me to understand the need to do more research in clinical areas in order to have a better treatment options for both acute management and chronic diseases. The best drug today for disease treatment may not be the best treatment in 10 years time as there would potentially be a drug that is safer and has more efficacy than the current best.

No new clinical science discovery means the end of new drug development. Most clinical questions can be answered only from good and high-quality research either for drugs or intervention. So, most of the time you will look at current research in the journal publications in order to find answers. I do that most of the time.

You were recently announced as the Top Recruiter for a paediatric study (RESPIRE). Can you share with us what it takes to ensure successful recruitment of a clinical trial?

To have a good and experienced team to do research is one of the main challenges. I would not be able to do everything on my own. Most of us feel that our official clinical duty is already too much of a burden. I try to overcome this by getting them interested in clinical research; I invest on creating highly skilled co-investigators and research assistants by providing them quality training and opportunities. Currently, I have at least 10 of them on my team that are willing to participate in conducting clinical trials. We work closely together and have specific roles delegated when there are ongoing clinical trials. Clinical Research Center (CRC) and Clinical Research Malaysia (CRM) have provide amazing access to the training which should not be wasted and ignored.

It can be stressful to manage the limited time and the high work load we have. Hence, we need to organize our work and create time and space for it. Pre-screening the subjects helps the trials to run smoothly and enables us to achieve our target much easier. I also feel that the involvement in research provide an opportunity for me to do something I like and enjoy. I believe this can be considered as part of my productivity to Ministry of Health of Malaysia to be part of the research landscape. As I believe, productivity is about "knowing what you want to do, intending to do it, doing what you wanted to do and see the results".

What is your motivation behind conducting clinical trials?

The answer is PASSION and INTEREST. Often, I use research as a platform to provide an option to treat patients who are no longer on treatment or has access to new treatment.

What one word best describes your career as a clinical researcher / investigator? Why?

Satisfaction. Once a research has been completed, I felt like I have proven to myself that I have reached my goal that was set at the beginning of the research involvement. I want to set an example to junior doctors that as clinicians, we can still become a clinical researcher and play an important role to actively participate in clinical research.

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

As one of the main players that provides high quality research centres and investigators globally. CRC and CRM are 2 important bodies that will enhance and bring more research to our country.

What changes would you like to see being made by the policy makers to create a more conducive ecosystem for the conduct of clinical trials in Malaysia?

For clinicians who are interested to do research – especially for investigator-initiated research – a specific/protected time should also be allocated to them to carry out the research and do the write up for journal publications. This should be for both investigator and industry-sponsored clinical trials. Investigators with successful publication at international congress or high impact journal should be given some incentives in the form of educational grants.

30 JANUARY

MOU BETWEEN FAHZU AND CRM

20 APRIL

MOU BETWEEN HEMATOGENIX, NOVOTECH AND CRM

6 AUGUST

MOU BETWEEN FIND AND CRM

25 - 29 AUGUST

ESC 2018 | MUNICH

SIG

MOU BETWEEN INTELLIM CORPORATION AND CRM

23 MARCH

DIA 2018 | BOSTON

24 - 28 JUNE

NURTURING NEW TALENTS IN ISR – SPECIAL SERIES WITH DR ALBIRUNI RAZAK

15 AUGUST

CLI
DA
RE

CRM
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2018 ROADMAP

HIGHLIGHTS

7 SEPTEMBER

GNING CEREMONY FOR CRM EDUCATION SCHOLARSHIP AGREEMENT

19 - 23 OCTOBER

ESMO 2018 CONGRESS

28 NOVEMBER

MOU BETWEEN IQVIA'S EARLY PHASE ONCOLOGY NETWROK (EPON) AND CRM

17 DECEMBER

CRM MOVED TO NEW OFFICE SUEZCAP, KL GATEWAY

NICAL TRIALS AY & 2ND IKN SEARCH DAY 2018

5 SEPTEMBER

CRM FIRST BOARD OF DIRECTORS MEETING WITH YB DATUK SERI DR DZULKEFLY AHMAD (HEALTH MINISTER)

16 OCTOBER

CRM'S SEMINAR IN JAPAN 2018

6 NOVEMBER

JAPAN CLINICAL TRIAL ONCOLOGY GROUP (JCOG) VISIT TO CRM

20 DECEMBER

HOSPITAL RAJA PEREMPUAN ZAINAB II

Hospital Kota Bharu was established in the 1920s. In remembrance of the late Sultanah Kelantan, this tertiary care facility name was changed to Hospital Raja Perempuan Zainab II (HRPZII) and the ceremony was officiated by Kebawah Duli Yang Maha Mulia Al-Sultan Kelantan Tuanku Ismail Petra Ibni Almarhum Sultan Yahya Petra on 5 September 2005. HRPZII is the main referral centre for the entire state of Kelantan and Northern District of Terengganu. The undergraduate medical students from University Sains Malaysia (USM) and Post Graduate Distance Learning Program (PJJ) doctors use HRPZII for their practical training, as well as trainees preparing for examination conducted by Universiti Kebangsaan Malaysia (UKM), USM and professional bodies overseas. Basic and post basic training for paramedical personnel are conducted as in-service training for all staff. In addition, HRPZII was recently appointed as a Regional Hub for Telemedicine, Regional Referral Centre for Psychiatry service and Regional Clinical Research Centre (CRC).

OUR FAMILY

- 146 Specialist
- 340 Medical Officer
- 386 House Officer
- 121 Pharmacist
- 1,708 Nurse
- 3,702 Total Staff

POPULATION SERVED IN 2017

- 13,571 Birth
- 67,985 Inpatient
- 316,879 Outpatient

HOSPITAL FACILITY

- 964 Bed
- 35 Wards

SPECIALTY

- Accident & emergency
- Anesthesiology
- Dermatology
- Forensic
- Medical
- Nephrology
- Obstetrics & Gynaecology (O&G)
- Ophthalmology
- Oral surgery
- Orthopaedic
- Otorhinolaryngology
- Pathology
- Pediatric
- Psychiatry
- Radiology
- Rehabilitation
- Surgical

Evolution of CRC Kelantan

2002 - CRC Hospital Kota Bharu created and operated as one of the quality activities at hospital level.
2007 - Renamed to CRC Kelantan and has expanded its scope of services to state level.
- Operates as an independent unit and is listed among other units and departments at HRPZII.
2013 - CRM SC joins in as part of CRC Kelantan
- Officially selected as 1 out of 11 IQVIA (previously known as Quintiles) Prime Sites.
2015 - CRC Kelantan office relocated to hospital staff quarters.
- Comprises of 2 treatment rooms/clinics and research room used to conduct Industry Sponsored Research (ISR) and Investigator Initiated Research (IIR).
2017 - Addition of CRC office space, SIV/monitoring room, Head of Unit room, staffroom, record room and tutorial room.
2018 - Officially selected as PARAXEL Preferred Site.

Total staff	: 19
Specialist	: 2
Medical officer	: 2
Pharmacist	: 1
Research officer	: 1
Nurse	: 2
Administrative officer	: 1
Contract Officer	: 1
CRM Study Coordinator	: 7
Freelance Study Coordinator	: 2

Services

Consultation
- NMRR online registration
- Protocol & proposal development
- Literature search / review
- Review of Research Protocol for IIR
- Statistical consultation
- Manuscript and abstract write up
- Assist in submission of research papers
- Assist in grant application

Training
- Good Clinical Practice (GCP)
- Introduction to Clinical Research (ICR) Workshop
- Statistical Analysis Workshop
- Study Coordinator Workshop
- Research Methodology Workshop
- Scientific Writing Workshop
- East Coast Research Camp
- Other research related courses

Facilities


Meeting Room


Cold-chain Room


Monitoring Room


Treatment Room / Clinic


Speciment Processing Room

START UP TIMELINES, METRICS, QUALITY AND ACHIEVEMENTS

Average Days

Start-Up timelines: <75 days
Quality: 94.8% (IQVIA Spotfire 19th Oct 2018)
SIV to FPFV: <60 Days
Contract Executed timelines: 30 days

STANDARD OPERATING PROCEDURES (SOP)

- Availability of CRM SOPs at site enable site to use it as reference/guide for the conduct of clinical trial.
- Each CRM SCs are certified, and they can train other hospital site staff on the proper conduct of clinical trial.

IQVIA PRIME SITE

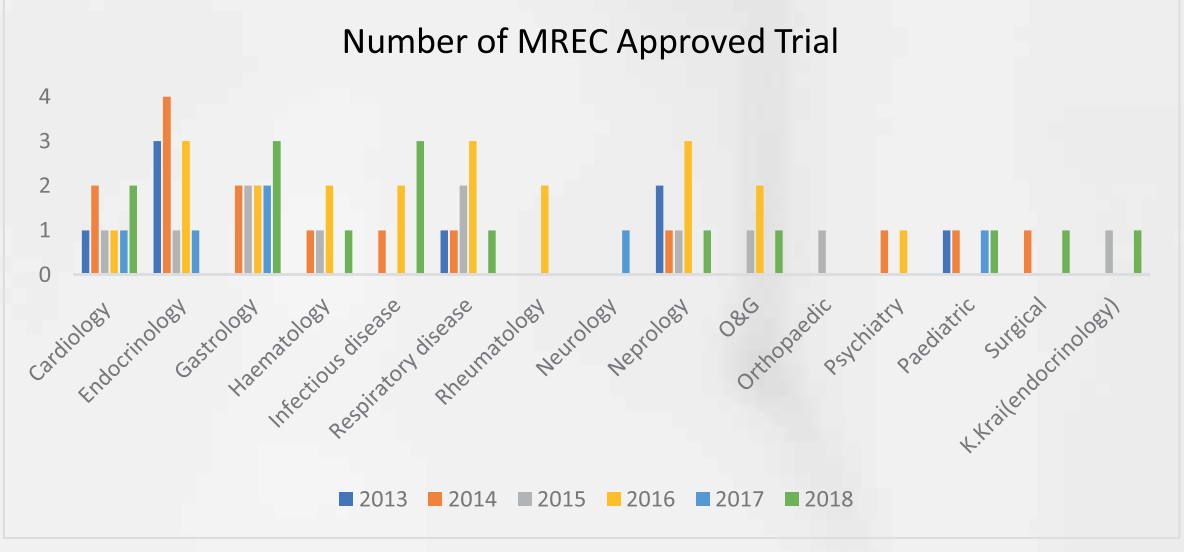
- Hospital Raja Perempuan Zainab II was selected as one of the 11 Prime Site in Malaysia in 2013
- This partnership enables to benchmark Malaysia with other global countries for these contributing factors; increase number of clinical trial, improve start up timeline, High quality and meet/exceed patient recruitment targets.

PAREXEL PREFERRED SITE

- Officially selected as PAREXEL Preferred Site on 21st Nov 2018.
- Objective: to outline the preferred site strategy, better understand site's areas of therapeutic interest, capabilities, capacity and infrastructure and explore whether there are areas of mutual interest.
- Ultimately, if both parties felt there was a desire for, and benefit in, a more strategic collaboration, PAREXEL would work with site's leadership team to increase the flow of clinical trial opportunities to site, identity a relationship manager within PAREXEL to oversee the collaboration and agree how best to optimise communication and processes between the two parties.

HRPZII awarded for Highest Number of Newly Approved Endocrinology Clinical Trials in Year 2016

CRM has successfully achieved the accreditation for ISO 9001:2015



HEPATITIS C ELIMINATION THROUGH ACCESS TO DIAGNOSTICS (HEAD-START) COMES TO MALAYSIA!

Q&A WITH SONJELLE SHILTON, PROJECT MANAGER FOR THE HCV PROGRAMME

I joined FIND in 2017, and took on the role of Project Manager for the Hepatitis C Elimination through Access to Diagnostics (HEAD-Start) project earlier this year. The majority of my career has been in Africa, where I spent 10 years as the Director of Operations of a community-based health outreach organization, HardtHaven, in rural Ghana – which showed me how critical it is that public health interventions be collaboratively designed and implemented with rigorous and meaningful data capture. If you don't measure it, you can't see if it's making an impact. I brought my experiences from Ghana to the monitoring and evaluation team at Gavi, the Vaccine Alliance, where I coordinated multi-country, multi-year, prospective full-country evaluations before joining FIND. I hold a Master of Global Public Health and the Global WACh Graduate Certificate in Integrated Health of Women, Adolescents and Children from the University of Washington, USA.

Sonjelle Shilton, Project Manager for the HCV Programme

Can you tell us a little more about FIND? Why are diagnostics so important?

FIND is a global non-profit organization that drives innovation in the development and delivery of diagnostics to combat major diseases affecting the world's poorest populations. It is astounding to see how often diagnostics do not exist, are inaccessible, or cost too much. This needs to change: not only do diagnostics tell patients what is wrong with them, they allow patients to be linked to the right treatment. Plus they are essential to a fully functional health system for many reasons, including surveillance to detect disease patterns and inform public health decisions. Diagnostics also play an important role in the research and development of drugs and vaccines.

What is the HEAD-Start project all about?

Hepatitis C is an emergency – 4 out of 5 people with the virus are unaware that they have it, and the mortality rate is rising. Diagnostics exist but they are generally limited to specialist laboratory use, and not getting to the people who need them. A complicating factor is that hepatitis C predominantly affects at-risk or marginalized populations, like people living with HIV, and those who inject drugs. Our HEAD-Start project, funded by Unitaid, is working to improve diagnosis of hepatitis C by simplifying the testing process and making diagnostics more affordable and more widely available. We're aiming to generate data that will help to drive a change in global implementation guidelines and national policies in support of the World Health Organization elimination targets for 2030.

Malaysia has declared hepatitis C to be a national health priority. How is HEAD-Start contributing to Malaysia's efforts to tackle this disease?

The Malaysian government is showing the world how to tackle hepatitis C – we believe Malaysia should be a model and source of inspiration that other countries in the region can look to as they scale up their own HCV responses. It was therefore really important for us to include Malaysia in HEAD-Start, and it is the only high-middle-income country covered by the project. Earlier this year we signed a Memorandum of Understanding with CRM to collaborate in the research and development of an innovative hepatitis C diagnostic testing strategy that we hope will lead to more cost efficient and earlier detection of hepatitis C.

Can you elaborate on the diagnostic challenges for hepatitis C?

In many countries, including Malaysia, health services are largely centralized – which broadly speaking means diagnostic services for hepatitis C are available in hospitals or laboratories, but not at the primary care level or in community healthcare settings where people first access health services. HIV testing sites offer some of the most accessible testing services, and we believe that integrating hepatitis C diagnostics into this existing infrastructure could be a game-changer for reaching people with hepatitis C/HIV coinfections, in addition to those who inject drugs.

What does that mean in practice? How will you make tests available in primary healthcare settings and what will happen to those who get a positive diagnosis?

We are working to demonstrate the feasibility of using new, rapid diagnostic tests in decentralized primary healthcare facilities, and provide technical assistance to the Malaysian Ministry of Health for their implementation. This work is being conducted in partnership between FIND and the Drugs for Neglected Diseases initiative (DNDi). Both FIND and DNDi are product development and delivery partnership organizations, so it's in our DNA to value collaboration on projects that facilitate equitable development along the entire care cascade. People who test positive for hepatitis C will be offered treatment in one of two ways. They can either join an ongoing DNDi clinical trial, which is co-sponsored by the Malaysian Ministry of Health and designed to assess the efficacy and safety of a new, alternative treatment regimen combining sofosbuvir with the investigational drug ravidasvir. Initial results from the first stage of this trial have indicated extremely high cure rates, including hard-to-treat cases. Alternatively, they will enter the Malaysian national hepatitis C programme, which now offers free treatment (sofosbuvir/daclatasvir) in 22 government hospitals.

Mainstreaming May Improve Access to Ovarian Cancer Genetic Testing in Malaysia

By Ms. Yoon Sook Yee, Cancer Research Malaysia

Mainstreaming may improve access to ovarian cancer genetic testing in Malaysia and help identify mutation carriers who may benefit from risk management and targeted treatment, suggests preliminary results of the MaGiC Study presented at the ESMO Asia 2018 Congress.

"Screening for BRCA1 and BRCA2 mutations is recommended for all patients with non-mucinous ovarian cancer," said lead author Ms Sook-Yee Yoon, Genetic Counsellor, Cancer Research Malaysia, Subang Jaya, Malaysia. "Genetic testing identifies mutation carriers and triggers appropriate risk management and treatment. In Malaysia BRCA genetic testing and counselling is only available at specialised centres in Kuala Lumpur but most people live outside the capital."

The Mainstreaming Genetic Counselling for Genetic Testing of BRCA1 and BRCA2 in Ovarian Cancer Patients in Malaysia (MaGiC Study) was set up to: 1) assess the prevalence of germline BRCA1 and BRCA2 mutations among ovarian cancer patients; 2) determine the feasibility of mainstreaming of genetic testing and counselling at local hospitals; and 3) examine the psychosocial impact of genetic testing in Malaysia.

The study was designed to recruit 800 ovarian cancer patients over a three-year period. Basic genetic counselling workshops were held for 60 non-genetic clinicians from 25 hospitals across Malaysia. Patients are counselled by a trained non-genetic clinician in their local hospital in a clinical programme led by Professor Yin Ling Woo, MaGiC's lead clinician, or by a genetic counsellor or clinical geneticist in a programme led by Professor Meow Keong Thong, who is the lead clinical geneticist at specialised centres in Kuala Lumpur.

All blood samples are analysed for BRCA mutations by Cancer Research Malaysia, led by Dr Joanna Lim who is the diagnostic lead. Patients receive pre-test counselling, followed by test results and post-test counselling. After both pre-and post-test counselling they are interviewed by a study researcher over the telephone to assess feasibility and the psychosocial impact of the experience. Interviews are based on scales adapted for use in Malaysia, including the Genetic Counselling Satisfaction Scale, the Decisional Conflict Scale, the Psychosocial Aspects of Hereditary Cancer (PAHC) questionnaire, the Distress Thermometer, and the Cancer Worry Scale. Interview results are being compared between the two counselling processes.

Two years into the study 476 patients have been recruited, of whom 445 received genetic testing and 59 (13%) had BRCA mutations.

"Around 13% of those tested were BRCA mutation carriers which is quite similar to that found in other populations," said Yoon. "We found carriers throughout the country and are working with local clinicians to establish protocols in local hospitals that have not managed patients with known BRCA mutations before, thus building capacity in multidisciplinary teams for high risk management of breast and ovarian cancer risk.

In terms of feasibility, patients in the local and specialised counselling arms were equally satisfied with the counselling they received. The local counselling arm has been recruiting patients more quickly than the specialised arm. Yoon said: "Patients seem to prefer local appointments, so if they are referred to another centre for genetic counselling, they seem less likely to attend."

Preliminary results show that the answers to the psychosocial surveys were similar between the two groups. Most patients were satisfied with their counselling experience, felt informed about their choices, and found it easy to decide to go ahead with genetic testing. Yoon said: "These are preliminary results but mainstreaming of genetic counselling in Malaysia may be a feasible model to improve access to genetic testing services or patients with ovarian cancer. If successful, this model could be adopted for other cancers and in other parts of Southeast Asia."

"Cancer is still a taboo subject in Malaysia and there is a fatalistic attitude to hereditary conditions," continued Yoon. "Genetic information can cause conflict in families and the data we are collecting on the psychosocial impact of genetic testing will provide insights into the psychosocial challenges. With this knowledge, we can focus on interventions to overcome these challenges."

In addition, in the past, genetic testing in ovarian cancer was limited to a small number of patients with the aim of identifying relatives at risk. Now that there is a drug that can potentially treat cancer patients with BRCA mutations, genetic counselling and testing may be requested by many more patients with epithelial ovarian cancer. This may increase the number of patients who qualify for testing and specialised centres may become overloaded.

DND*i* NEWER, SIMPLER TREATMENTS FOR SLEEPING SICKNESS

Conducting clinical trials in remote and unstable areas

Photo: Neil Brandvold - DND*i*

The journey to the sleeping sickness trial site in Isangi from the DND*i* office in Kinshasa begins in the domestic airport of DRC's capital city and ends more than a day later halfway across the country in a barge crossing the Congo river. In between: hours spent navigating potholed dirt roads, collapsed bridges, checkpoints, and multiple river crossings. Once at Isangi, canoes must be used to reach many of the patients as there are no roads.

Yet for DND*i*'s clinical team in DRC, Isangi is one of the easier-to-reach sites. The DRC and the Central African Republic (CAR) both pose daunting challenges that must be overcome to develop better treatments for patients suffering from sleeping sickness.

The DRC and the Central African Republic (CAR) both pose daunting challenges that must be overcome to develop better treatments for patients suffering from sleeping sickness.

Political instability is a major challenge. Armed conflict in CAR forced DND*i* to stop recruitment of patients in 2013. "Despite this constraint, we managed to follow-up more than half of the patients who had been treated," says Dr Francis Regongbenga, Principal Investigator for CAR at the Batangafo site.

A second important challenge is infrastructure. It is imperative that wards, labs, and other facilities conduct clinical research that is up to par with "Good Clinical Practice" (GCP).

Clinical trial sites were brought up to these standards – not a small task considering their remote location. Nine referral treatment units were renovated and refurbished, with solar energy equipment and generators installed. Equipment was brought in: new microscopes equipped with cameras and Piccolo analyser – a fully automated system for blood testing and defibrillators. Internet access was installed to enable transmission of case report forms, particularly necessary for the monitoring of safety parameters.

DND*i* NEWER, SIMPLER TREATMENTS FOR SLEEPING SICKNESS

"With the fexinidazole clinical trial, everything changed. Not only does our hospital no longer look like a farm, but the community benefits from a modern facility and our work is easier," says Watson Tawaba, nurse at the Bagata site in DRC.

Overcoming the lack of trained staff is another hurdle. Through the HAT Platform – a clinical research network to strengthen capacities in endemic regions set up with the support of DND*i* in 2005 – trainings were provided in diagnostic and treatment procedures, pharmacovigilance, GCP guidelines, and even medical waste management.

The joint experience of DND*i* and the national sleeping sickness programme in the DRC shows it is possible to build an environment conducive to running quality clinical trials. These efforts build and sustain the capacity to conduct a high standard of clinical research in endemic countries, but they also bring lasting benefits to researchers, staff and hospitals, as well as to health systems more broadly, and thus ultimately to local communities and patients.

Photo: Neil Brandvold - DND*i*

Journey to success in Phase 1b Clinical Study for Hepatitis B at the University Malaya Medical Centre

By Chan Wei Quan, Site Manager, Global Clinical Operations (GCO) Malaysia, Janssen

If you were diagnosed with chronic hepatitis B, would you be willing to try an experimental compound developed by a world-renowned pharmaceutical company? On one hand, you may be hesitant but on the other, you may want to know more about it. For novel compounds to be approved for use in the market, pharmaceutical companies go through a period of pre-clinical and clinical phases to evaluate the compound's effectiveness. To achieve this, volunteers are needed!

Based on statistics generated by Clinical Research Malaysia (CRM) on phases of clinical trials that were conducted in Malaysia for the year of 2017, Phase 3 studies topped the chart. Whereas for Phase 1 studies, a total of 5 Phase 1b studies were conducted in Malaysia. Is Malaysia too reserved in exploring Phase 1 studies? As a matter of fact, Malaysia has recently released a Phase 1 clinical guideline as well as a Phase 1-unit inspection and accreditation program. Malaysia is now one step closer to conducting more first-in-human (Phase 1) research. Thanks to the groups of regional key opinion leaders in initiating the Phase 1 realization project (P1RP), afflicted patients in Malaysia now have access to new treatment options and regimens. Furthermore, this allows room for economic growth as clinical research could be one of its main drivers as mentioned by the previous Malaysian Health Minister, Dr. Subramaniam. A little elaboration on what Phase 1 study is. Phase 1 study is to primarily to determine what dosage is safe and how treatment should be given. Dosage may be given in single ascending dose/multiple ascending dose. The target population is usually healthy volunteer and study is conducted in small scale. You may search for "Phase 1" to know more……

Chronic Hepatitis B (CHB) is one of the most alarming diseases that has captured the attention of the public health globally. One of the common infections by the hepatitis virus, CHB is often linked with major psychosocial issues due to social stigma. In Malaysia, a multicultural country in Asia, the CHB carries rate varies depending on ethnicity and gender. According to Raihan R (2016), CHB accounts for more than 80% of the hepatocellular carcinoma (HCC) cases seen in Malaysia, and HCC is the third most common type of malignant neoplasm and among the top ten leading causes of death. Following the implementation of the nationwide hepatitis B vaccination in 1989, there was a steady decline of CHB. There is currently no cure to hepatitis B and CHB patients require a daily medication regimen to suppress the hepatitis B viral load. This duration of this regimen is indefinite with the risk of patients developing side effects over the long run. There is an unmet medical need to a CHB cure and this has been the central focus of many pharmaceutical companies. There are several pharmaceutical companies working to develop a cure for CHB. Any

of these companies wanting to conduct a trial in Malaysia would know that Prof Dr. Rosmawati Mohamed is a leading key opinion leader in this field.

While managing the Phase 1b trial (namely HPB1001) clinical study in Malaysia, I had the privilege of working with a renowned hepatologist from the University Malaya Medical Centre (UMMC), Prof. Rosmawati Mohamed. The novel compound may or may not confer therapeutic benefits to the patient, however, the eagerness to look for a functional cure and to improve CHB patients' quality of life for Prof Rosmawati prevailed. Prof Rosmawati as the principal investigator (PI) headed a team comprising Dr. Roma Basu and Dr. Abdul Malik (sub-investigators), in addition to Dr. Syed Mukhtar and Dr. Zainab Abu Kassim (study coordinators). During this time, Prof. Rosmawati and her team dedicated valuable time and effort in screening for suitable patients. Patients needed to be diagnosed with CHB, but also had to be relatively well in terms of medical health. Furthermore, patients needed adhere to protocol procedures and restrictions while being compliant to prohibited and allowed concomitant medications. At the end of the recruitment period, Prof Rosmawati and her team managed to recruit five patients into the HPB1001 study, ranking Malaysia as the second-best recruiter globally, and ahead of a few countries known for well-established Phase 1 experiences. This achievement puts Malaysia in the limelight as a rising competitive country in conducting Phase 1b trials, despite being initially considered naïve country in Phase 1 studies.

Clinical trials are unable to commence without the approval from a local ethics committee (EC). Moreover, clinical trial proposals submitted to the EC may sometimes warrant justification from the PI on the risk-benefit assessment for conducting such a clinical trial (termed a EC defense meeting). The HPB2001 trial was one of the proposals requiring further clarification, for which Prof. Rosmawati defended excellently. Her effort in defending the proposal during the meeting ensured that the study was approved by the EC on time, allowing for country and global milestones to be met.

Prof Dr Rosmawati awarded the "Top recruiter In Asia – Phase 1b: Session XI" Dr Syed Mukhtar awarded with certificate of appreciation in ensuring study quality

Another important aspect of clinical trials is the generation of quality data. Data is collected each time the patient makes a visit to the hospital. This data is compiled and analyzed on a global level, allowing further adjustments to protocols as required. This data is eventually required for the submission to the health authorities for drug approval and marketing. For the HPB2001 trial, Pros. Rosmawati showed great perseverance in ensuring the timely entry of patient data as well as implementing effective retention strategies for the patient during the three-month study period. Prof. Rosmawati managed to retain all of her enrolled patients in the HPB2001 clinical study, symbolizing a mark of excellence.

In this highly regulated industry, subject safety, data integrity and quality are of the utmost importance. In August 2018, the Malaysia Health Authorities, the National Pharmaceutical Regulatory Agency (NPRA) conducted a three-day inspection for the HPB1001 at UMMC. The outcome was favorable with no major findings or observations noted. The results of this inspection are not only a reflection of Prof. Rosmawati's dedication to conducting the HPB2001 trial but is also a form of favorable validation on the quality of the research. Furthermore, the success of the inspection is also attributed to the Clinical Investigation Centre (CIC), a clinical department at UMMC dedicated to conducting clinical trials.

Clinical research is a necessary step in sourcing alternative treatment options to many diseases. CHB is one of these diseases. The success of clinical research is largely dependent on the clinical study team chosen to manage it. However, aside from the study team, an even more pivotal element in ensuring the success of clinical trials are the patients. Patients who join the trials allow the generation of data, which in turns leads to more data contributing to the approval of the drug and eventually its availability to the community, hence bringing more benefit to more patients. The willingness of patients who volunteer in the early drug development phase is deserving of commending respect, despite the limited safety and efficacy data generated from pre-clinical studies. Their commitment to clinical trials is regarded as a major contribution in accelerating the development and approval of experimental treatment options. The "I AM AWARE" campaign, designed to increase awareness of clinical research in Malaysia is currently underway. These campaigns conduct regular roadshows at government hospitals and also happen to be a good source of information pertaining to clinical research.

Reference:
Raihan R. Hepatitis in Malaysia: Past, Present, and Future. Euroasian J Hepato-Gastroenterol 2016;6(1):52-55

Signing Ceremony for CRM Education Scholarship Agreement, 7 September

Penang Research Day 2018, 14 September

Sabah Research Day 2018, 22 September

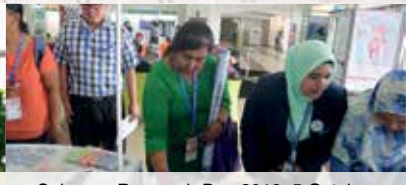
NCCR 2018, 24 September

Investigator Dialogue 2018, 26 September

4th National AIDS Conference 2018, 29 September

Visit to NUHS, Singapore, 9 October

Visit to IQVIA Singapore, 9 October



Selangor Research Day 2018, 5 October

2nd Board of Directors Meeting for 2018, 16 October

ESMO 2018 Congress, 20 October

Perlis Research & Quality Day 2018, 30 October

CRM Industry Dialogue2018/2, 17 October

CRM in Photos

2nd NERCIM Meeting for 2018, 22 October

Courtesy call to Vice Minister for Health, Labour and Welfare, Japan, 6 November

CRM's Seminar in Japan 2018, 6 November

Meeting with Japan Pharmaceutical and Medical Device Authority, 6 November

REACTA Forum 2018, 11 November

World Innovation Summit for Health (WISH) 2018, 13 November

Nurturing New Talents in ISR – Gastroenterology, 22 November

2nd Prime Site Joint Steering Committee Meeting, 28 November

Meeting with Tranz-Life and Jigsaw Clinical Research Solutions, 27 November

Nurturing New Talents in ISR - Haematology, 14 December

Visit by Bayer (South East Asia) Pte Ltd, 18 December

Visit by NPRA team, 19 December

Visit by JCOG and intellim Corporation Inc., 20 December

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