By Clinical Research Malaysia

CRM bulletin

of Clinical Research and Therapy

ISSUE 09

Making sense of the Statistics
Hepatitis C: The Silent Epidemic

Knowing Clinical Trials
Size Matters

Research Personality
Dr. Tan Soek Siam

Moving Towards Affordable HEPATITIS C Treatment

ABOUT CLINICAL RESEARCH MALAYSIA

Clinical Research Malaysia (CRM) is a non-profit company wholly owned by the Goverment 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

CRM
CLINICAL RESEARCH MALAYSIA
Your Global Solutions in One Nation

FROM THE CEO's DESK

June 2016 marked the 4-year anniversary of CRM being operational, certainly a significant milestone in our evolution towards advancing global health solutions for a brighter, more hopeful future for the people by providing speedy and reliable end-to-end clinical research support for quality studies. The major projects involving CRM this year is the Phase I Realization Project (P1RP), the Hepatitis C study under the Drugs for Neglected Disease initiative (DNDi) and preclinical work involving the Institute of Medical Research (IMR).

The P1RP initiative that is spearheaded by CRM marks an important milestone in the history of clinical research in Malaysia. This project was designed as the Malaysian government wishes to push its involvement in all phases of drug development, and in this case for Phase I trials. The 5 pillars that layout the P1RP blueprint include the development of Malaysia's phase I clinical trial guideline, people development, capability development, preparation of sites and risk management. This initiative that started in May 2016 will see the completion of the Phase I clinical research ecosystem in 2019. We believe that the capture of Phase I trials may result in a spill over effect of more later phased trials into Malaysia.

CRM is also currently in collaboration with DNDi, a not-for-profit research and development organization that works to deliver new treatments for neglected diseases. CRM works with the Ministry of Health and DNDi by supporting clinical studies on hepatitis C. The clinical study will further ensure equitable access to effective treatments for patients suffering from this disease in Malaysia. The study is already taking place in five Ministry of Health (MoH) hospitals and 1 university hospital.

The pre-clinical work although in progress with IMR will certainly complete the ecosystem of clinical research from pre-clinical to clinical research. The humble beginning starts with collaboration with foreign universities on projects related to dengue virus. The path forward having been lighted, CRM will certainly have its hands full over the foreseeable future in seeking to create the right clinical research ecosystem through its collaboration with the industry, government ministries, regulatory authorities and investigators.

The whole CRM TEAM is prepared to take any new challenge ahead, and will continue to strive for greater heights. Together Everyone Achieves More (TEAM).

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

Contents

CRM Create Waves at DIA 2016 Annual Meeting

27 June 2016, Philadelphia – CRM participated in DIA 2016 held in Philadelphia, Pennsylvania, USA from 27 – 29 June. DIA is the largest global interdisciplinary event that brings together key thought leaders and innovators from industry, academia, regulatory and government agencies, health, patient and philanthropic organizations from around the globe. The three-day event attracted about 300 delegates to CRM's booth, where they found information on Malaysia's clinical research ecosystem and CRM's services. The event brought together 7000 professionals, delegates from over 50 countries and a total of 450 exhibitors.

All About Big Data in the 10th NCCR

27 July 2016, Kuala Lumpur – The 10th National Conference for Clinical Research (NCCR) was held at Hotel Istana, Kuala Lumpur with the theme "Big Data Driving Clinical Research for Health".
The event, supported by Clinical Research Centre (CRC) in collaboration with Clinical Research Malaysia (CRM) and the Society for Clinical Research Professionals Malaysia (SCRPM), serves as a platform that brings scientists, researchers, medical and allied health professionals together to share and exchange research findings.This two-day conference was officiated by the Minister of Health, Yang Berhormat Datuk Seri Dr. S. Subramaniam on 28 July 2016.

Annually held, the 10th NCCR showcased a rich and varied programme, with 24 locally and renowned speakers from Malaysia, Singapore, Korea, Taiwan, Australia, the United Kingdom and the US. "Acknowledging the importance and impact Big Data can bring, the Ministry of Health (MoH) has started working on the Malaysian Health Data Warehouse (MyHDW) since 2010 where it is envisioned to meet the diverse needs of timely health information provision and management, and acts as a platform for the standardization and integration of health data from a variety of sources", said Datuk Seri Dr. S. Subramaniam in his speech, emphasizing the importance of big data in the research and healthcare sector. He notes that it is encouraging to see the participation and involvement of multidisciplinary teams from the Ministry of Health, and members of academia and hopes that all parties use this opportunity to exchange scientific ideas, inspire new research and forge long lasting partnerships in their respective field.

Malaysia is Progressing with the Phase 1 Realization Project (P1RP)

20 Aug 2016, Kuala Lumpur – The second workshop for the development of the Phase I Clinical Trial Guideline was successfully conducted last August and was attended by senior investigators, regulators and subject matter experts who sat as steering committee members. The development of the Phase I guideline marks an important step in the Phase I Realization Project (P1RP) blueprint which has four other pillars to it;

People Development, Capability Development, Preparation of Sites and Risk Management. The phase I clinical trial guideline will be launched in early 2017.

The first Phase I Clinical Trial Guideline Workshop was officiated by the Minister of Health, Datuk Seri Dr. S. Subramaniam on 20th May 2016. In his speech, he touched on the multiple economic advantages in opening Malaysia's doors to early phase studies. Among them are the transfer of knowledge and technologies to Malaysians, as many of these trials test cutting-edge treatments and technologies. Besides, local pharmaceutical and biopharmaceutical industries will also gain first-hand experience in ensuring the efficacy and safety of new drugs.

CRM Standing Alongside Malaysian Cardiologists in Rome

27 August 2016, Rome – The European Society of Cardiology (ESC) held from 27–31 August attracted cardiology experts from over 140 countries and recorded over 31,000 participants. This year's spotlight, 'The Heart Team' highlighted the importance of teamwork and interactions between all professionals and specialties involved in managing patients with cardiovascular disease. Exciting tracks were organised on surgery, stroke, and e-cardiology.

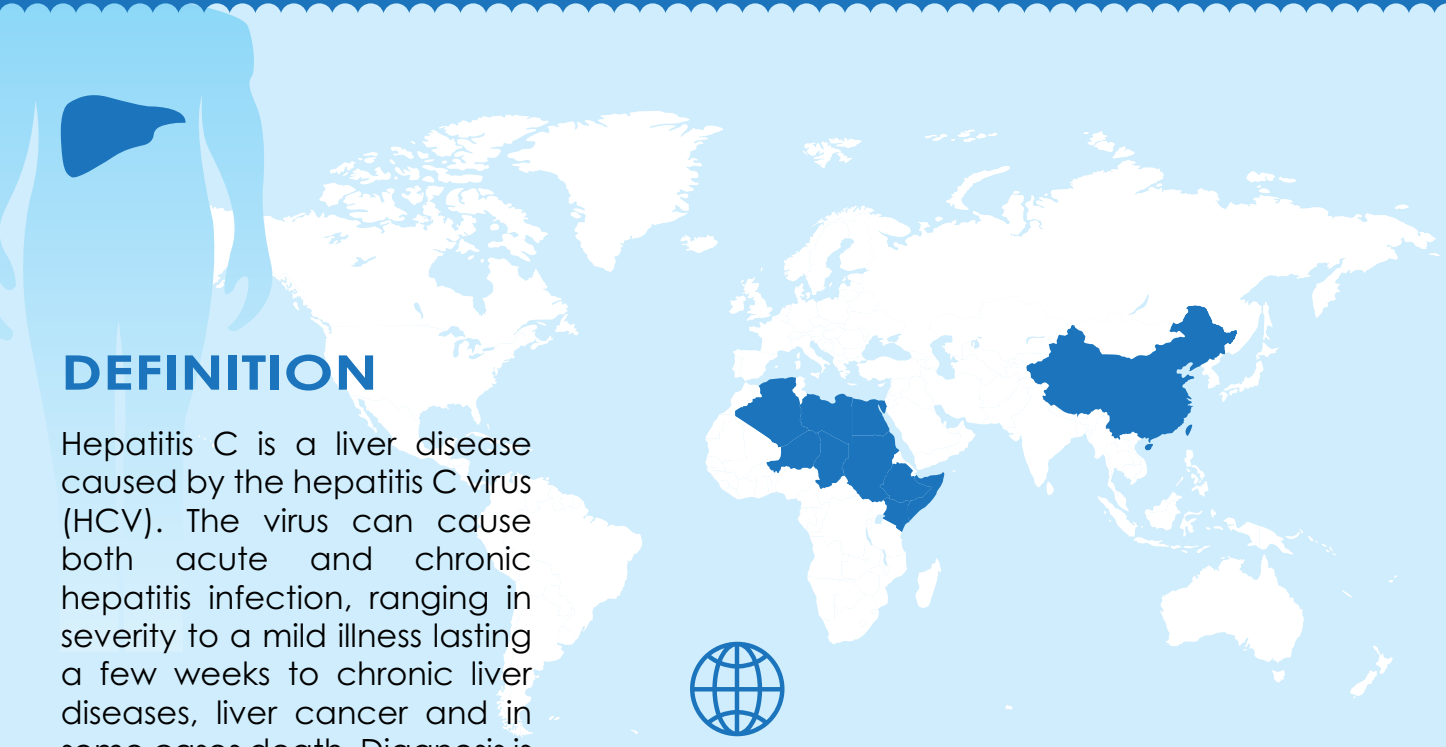
CRM exhibited its services from the stand, E2-F770 and received various visits of cardiologist and chest physicians around the globe who are actively involved in research. The CRM team in Rome shared Malaysia's ecosystem in conducting industry sponsored research (ISR) especially in cardiology clinical trials, and CRM's role as a one stop centre in facilitating clinical trials and research collaborations. This event empowered CRM to reach out to the research players from both the medical fraternity and industry to promote Malaysia's potential and the available resources to conduct ISR. ESC 2016 served as a platform for CRM to identify the needs of the industry players in conducting research and therefore to complement each other's services to leverage more ISRs into Malaysia.emphasizing the importance of big data in the research and healthcare sector. He notes that it is encouraging to see the participation and involvement of multidisciplinary teams from the Ministry of Health, and members of academia and hopes that all parties use this opportunity to exchange scientific ideas, inspire new research and forge long lasting partnerships in their respective field.

DNDi Wins President's Award at 2016 DIA

27 June 2016, Philadelphia – The Drugs for Neglected Disease initiative won the President's Award for Outstanding Contribution to Global Health during the 2016 DIA Philadelphia held from 27–29 June 2016. The Drugs for Neglected Diseases initiative (DNDi) is a patient-needs driven, not-for-profit research and development (R&D) organization that develops safe, effective, and affordable medicines for neglected diseases that afflict millions of the world's poorest people.

DNDi focuses on developing new treatments for the most neglected patients suffering from diseases such as sleeping sickness (or Human African Trypanosomiasis), leishmaniasis, Chagas disease, malaria, specific filarial diseases, and pediatric HIV. The initiative's primary objective is to deliver 11 to 13 new treatments by 2018 and to establish a strong R&D portfolio for these diseases.

HEPATITIS C THE SILENT EPIDEMIC



DEFINITION

Hepatitis C is a liver disease caused by the hepatitis C virus (HCV). The virus can cause both acute and chronic hepatitis infection, ranging in severity to a mild illness lasting a few weeks to chronic liver diseases, liver cancer and in some cases death. Diagnosis is made through blood testing.

There is no vaccination for Hepatitis C.

10X

Hepatitis C virus is 10 times more infectious than HIV

75%

About 75% of the infected population are unaware that they are infected with Hepatitis C

GLOBAL HEALTH BURDEN

Viral hepatitis is found worldwide. However, there is a higher prevalence in Africa and Eastern & Central Asia.

3 to 4 million new cases each year

700 000 people die each year from Hepatitis C

130–150 million infected worlwide

PATH FOR BETTER HCV MANAGEMENT

- Support Research & Development
- Increase Awareness and Prevention

Antiviral medicines can cure approximately 90% of persons with Hep C infection, but access to diagnosis and treatment is low.

TREATMENT INNOVATION

60 to 90%
of HCV infections can be cured. New treatments offer better cure rates, reduced treatment duration and fewer side effects.

MAIN ROUTES OF TRANSMISSION

- Unsafe injections
- Inadequate sterilization of medical equipment
- Blood transfusion
- Sexual transmission

Infection

About **15–45%** of infected persons spontaneously clear the virus within 6 months of infection without any treatment.

Chronic Disease

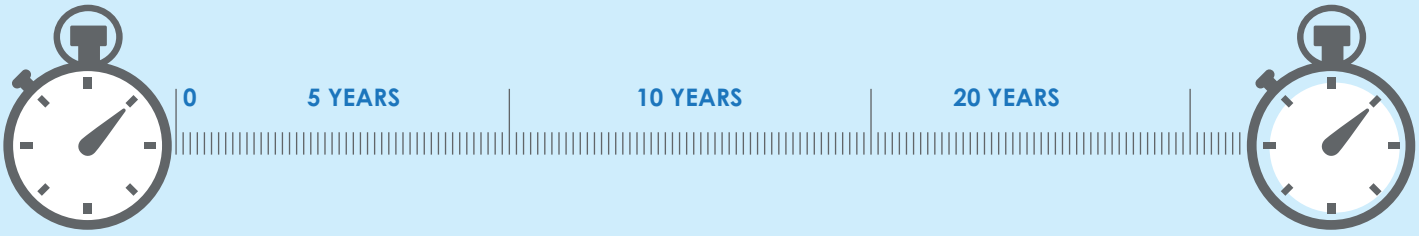
55 – 85% of people infected with HCV will develop chronic infection.

Cirrhosis

15 – 30% of people with chronic HCV infection will develop cirrhosis

Liver Cancer

HCV is the **n°1** cause of liver Cancer



- Improve Screening Availability
- Develop Policies & Allocate Resources

Source: World Health Organization

Hepatitis C tied to increased risk of Parkinson's

The hepatitis C virus may be associated with an increased risk of developing Parkinson's disease, according to a study published in the December 23, 2015, online issue of Neurology®, the medical journal of the American Academy of Neurology. Parkinson's disease is considered the second most common degenerative brain disorder after Alzheimer's disease. Hepatitis C is a liver infection caused by a virus. "Many factors clearly play a role in the development of Parkinson's disease, including environmental factors," said study author Chia-Hung Kao, MD, China Medical University in Taichung, Taiwan. "This nation-wide study, using the National Health Insurance Research Database of Taiwan, suggests that hepatitis caused specifically by the hepatitis C virus may increase the risk of developing the disease. More research is needed to investigate this link."

Source: American Academy of Neurology (Dec 23, 2015)

Dengue virus exposure may amplify Zika infection

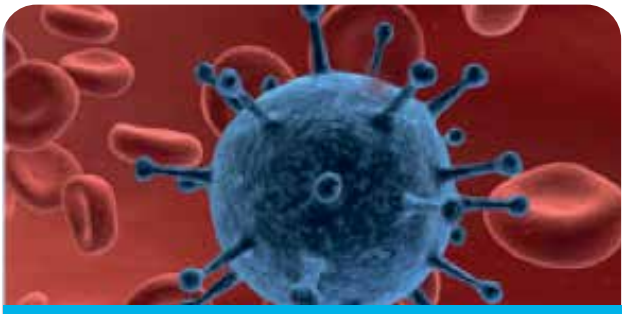
Previous exposure to the dengue virus may increase the potency of Zika infection, according to research from Imperial College London. The early-stage laboratory findings, published in the journal Nature Immunology, suggests the recent explosive outbreak of Zika may have been driven in part by previous exposure to the dengue virus.
The study, which included scientists from Institut Pasteur in Paris and Mahidol University in Bangkok, suggests the Zika virus uses the body's own defences as a 'Trojan horse', allowing it to enter a human cell undetected. Once inside the cell, it replicates rapidly.
Professor Gavin Screaton, senior author of the research and Dean of the Faculty of Medicine at Imperial, said: "Although this work is at a very early stage, it suggests previous exposure to dengue virus may enhance Zika infection. This may be why the current outbreak has been so severe, and why it has been in areas where dengue is prevalent. We now need further studies to confirm these findings, and to progress towards a vaccine."

Source: Imperial College London (June 23, 2016)

New drugs hope to fight neglected tropical diseases

Scientists say they are a step closer to providing effective treatments for three "neglected" diseases after making a chemical which can kill the parasites that cause the illnesses. Chagas disease, leishmaniasis and human African trypanosomiasis (also known as sleeping sickness) affect 20 million people worldwide and lead to more than 50,000 deaths annually.
The diseases are caused by infection from parasites which have some similar biology and genomic sequence, suggesting that all three diseases could be cured with a single class of drug. The scientists were able to identify an enzyme common to all three parasites and develop a chemical that binds to the "target" and prevents it from functioning.
The research, which was led by scientists from the Genomics Institute of the Novartis Research Foundation (GNF), included collaboration with colleagues at the Novartis Institute for Tropical Diseases (NITD), University of York, University of Washington and the University of Glasgow.

Source: University of York (August 8, 2016)



Viral hepatitis kills as many as malaria, TB or HIV/AIDS

Viral hepatitis has become one of the leading causes of death and disability across the globe -- killing at least as many people annually as TB, malaria or HIV/AIDS. This is the finding of new research from scientists at Imperial College London and University of Washington, who analysed data from 183 countries collected between 1990 and 2013.
Viral hepatitis exists in five forms -- A, B, C, D and E and is transmitted through bodily fluids, or, in the case of A and E, through food or drink contaminated with faeces. A majority of the deaths -- 96 per cent -- were due to hepatitis B and C which cause liver damage (cirrhosis), and liver cancer. Symptoms include fatigue, jaundice and nausea, however in many people the infection is symptomless -- and so an individual may not know they are infected until they develop serious complications.The researchers, who published their findings in journal The Lancet, found that viral hepatitis deaths increased by 63 per cent over the 23-year period.

Source: Imperial College London (July 7, 2016)

Sleeping sickness, chagas disease, leishmaniasis: A multitude of healthy carriers

Humans can tolerate the parasites responsible for the sleeping sickness, Chagas disease and leishmaniasis for many years. These parasites belong to the same family of pathogens known as trypanosomatids. Researchers have highlighted this tolerance phenomenon in humans, which results from the genetic evolution of the populations being exposed.They point out that healthy carriers actually represent the vast majority of people contaminated by trypanosomatids. It is imperative to take this previously overlooked natural reservoir into account in the public health programmes in order to eradicate these diseases by 2020, in accordance with the WHO's objectives.

Source: Institut de Recherche pour le Développement (IRD) (February 10, 2016)

People with hepatitis C are two to five times more likely to develop certain head and neck cancers

Long associated with liver cancer and non-Hodgkin's lymphoma, a study from The University of Texas MD Anderson Cancer Center reveals for the first time that the hepatitis C virus (HCV) is associated with certain head and neck cancers. The findings, published in the Journal of the National Cancer Institute, could have significant implications for both the screening of those with the virus and the treatment of those with head and neck cancers.

Source: University of Texas M. D. Anderson Cancer Center (April 13, 2016)

Rare disease gene has a key role in chronic hepatitis C infection

Hepatitis C virus (HCV) hijacks the host's fat metabolism for its own survival, growth, and transport in the human body. A study published on April 28th in PLOS Pathogens identifies a host gene involved in the formation of HCV virus particles and helps explain why humans with a rare mutation in the gene have problems with their fat metabolism.

Source: PLOS (April 28, 2016)

DR. TAN SOEK SIAM

Senior Consultant Hepatologist Department of Hepatology, Selayang Hospital, Selangor.

Dr. Tan Soek Siam is Senior Consultant Hepatologist and Head of the Department of Hepatology at Selayang Hospital. She is also the National Head of the Hepatology Service of the Ministry of Health (MOH). She obtained her medical degree at Trinity College, Dublin, Ireland in 1991. After completing her postgraduate exams, she returned to Malaysia to serve at both Hospital Raja Permaisuri Bainun and later on at Hospital Kuala Lumpur (HKL) where she began her hepatology specialty training. In 2000 to 2001, she undertook a clinical fellowship at the Institute of Liver Study at King's College Hospital, London.

Dr. Tan is president-elect of the Malaysian Society of Gastroenterology and Hepatology (MSGH). She is also a council member of the College of Physicians, Academy of Medicine Malaysia and also a member of the Malaysian Transplant Society.

She has published in several local and international peer-reviewed journals and a few book chapters. Dr. Tan has been invited to speak at various international meetings, besides being involved in over 34 industry sponsored and investigator initiated clinical trials. Her area of interests are in viral Hepatitis B and C, autoimmune hepatitis, fatty liver, decompensated and critically ill chronic liver diseases, acute/acute-on-chronic liver failure and liver transplantation.

Dr. Tan first became involved with clinical trials in the late 1990s when she was a trainee at HKL. At that time, she was a co-investigator and it was the advent of new oral drugs for hepatitis B. She recalled her excitement being involved in a ground-breaking clinical trial involving patients with very advanced liver disease in Asia, which included Malaysia.

The study found that the novel treatment could prevent the progression of liver disease in these patients, allowing them to live longer and have a better quality of life. It fulfilled her patients' unmet needs who in the past, had little treatment options and often did not live for very long. According to Dr. Tan, this study remains heavily quoted in medicine, and it has given hope to patients with advanced liver disease who are now still well and remain under her follow-up. This was the beginning of her interest in clinical trials.

When asked about her current research, she discussed a hepatitis C trial under the Drugs for Neglected Diseases initiative (DNDi) which is sponsored by the MOH through CRM. The study had recently completed investigators meeting and will be conducted in Malaysia and Thailand with a target competitive recruitment of 750 patients. She said that the study progress in Malaysian was well ahead, thanks inno small part to the efforts

of Clinical Research Malaysia (CRM) and Clinical Research Centre (CRC). The Malaysian arm of the trial is targeting a recruitment of at least 500 patients.

Hepatitis C treatment is undergoing a revolution just as hepatitis B did in the late 1990s. Cutting-edge medications will enable more hepatitis C patients to live better lives. This revolution is attributed to the background research done by scientists on the lifecycle of the hepatitis C virus. Discoveries have allowed the identification of novel target sites for hepatitis C drugs. Hepatitis C is now rendered curable thanks to these new drugs.

She said she felt truly fortunate being part of this study from the initial discussion starting in 2014 to the protocol writing and now a study that is about to start. The trial will determine an all oral drug regimen that is: effective (defined as able to cure more than 90% of patients), safe with minimal side effects therefore acceptable to many more patients, and easy to monitor while on treatment. She explained that hepatitis C viruses have many genotypes and in Malaysia, 98% of patients belong to only two genotypes (ie genotypes 1 and 3). If the compound is found effective in these two genotypes, many more patients can be treated very easily at a reduced cost and by many more clinicians without dependence on hepatologists.

"We hope this study will translate into a public health approach to control the burden of hepatitis C related diseases by reducing the number of people who may end up with liver cancer, people dying from liver problems, and the need for liver transplants in the country," said Dr. Tan.

As clinical trials require significant manpower, a big team is dedicated to the study at Selayang Hospital. The team comprises all 3 hepatology consultants, 5 trainee doctors, CRM study coordinators, and a few members of her staff, including pharmacists. A bigger team allows more study days per week to recruit more patients as the patient list is long and they need to be screened thoroughly before being accepted into the study.

The gravity of this trial for Malaysia is not lost on Dr. Tan. The results of the study will help guide the MOH on the future management of hepatitis C in the country. A lot is at stake but she remains optimistic because she has the support of the Ministry of Health, hospitals, university hospitals and senior investigators participating to help realise this opportunity to do a highly relevant study which may in turn pave the way on how clinicians manage the disease in the local setting.

Challenges are nothing new to her but a recurring theme in this line is the difficulty to recruit patients. Even with the best plans laid out at times it can be difficult to get even a handful of patients. She said that patient perception of a study has to be taken very seriously. At MOH hospitals, the medications are free and patients are very happy with their present level of treatment. There is a certain level of patient inertia, restraining them from participating in research to improve their current level of care, even if it could result in a cure.

In the past, patients were more receptive to trials because they had few treatment options. Patients were also more likely to listen and trust their doctors' recommendations. There are also other concerns hindering trial recruitment such as trouble taking time off work for appointments, complaints about traffic jams and parking. Some are influenced by their friends who say they are being used as 'guinea pigs'. These are obstacles to research but failing to recruit patients does not mean failure, there are lessons to be learned about patients' concerns and needs, she said.

Sometimes, doctors themselves are hesitant to partake in research. Dr. Tan expressed the difficulty she faced getting some of her juniors to participate in research. When she was a trainee, she jumped at the chance of taking part in a trial. She said research was an important part of her training and improved the way she practiced medicine. Getting patients into trials also gives her patients hope. She said participating in trials to find a better way to help patients was an exciting prospect, but getting her peers to be equally excited remains a challenge.

She said that CRM has been a crucial part of her clinical trial journey. When she first started years ago, most tasks were divided between the clinic's staff. Now, CRM's study coordinators have helped improved the efficiency of her trials many-fold and has been her "lifesaver".

CRM has built the foundations of Malaysia's clinical research, but Dr. Tan noted on the need to set up a comprehensive database of clinicians, investigators and subjects. Having a good patient database will improve researchers' access to potential trial subjects. She also suggested setting up a centralised laboratory system and facilities for serum or tissue storage, to further improve Malaysia's research efforts and competitiveness.

When asked about what policy changes she would like to see, she highlighted on the need for policymakers to recognise the efforts of people involved in research and to continue to support and encourage them in the research journey. Research (IIT and ISR) and service go hand in hand, one needs the other and they are the fuels for each other. Opportunities should also be provided to doctors to network with other like-minded people, which include the pharmaceutical industry and academia.

> ***We hope this study will translate into a public health approach to control the burden of hepatitis C - Dr. Tan***

Dr. Tan (National PI for DNDi Hep C study) and Dr. Haniza Omar (Site PI) with their study coordinators at Selayang Hospital.

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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

MALAYSIA HEALTHCARE

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Malaysia Healthcare, winner of the "Medical Travel Destination of the Year 2016" award at the International Medical Travel Journal's Medical Travel Award for two consecutive years and named "Best Country in the World for Healthcare" by International Living's Global Retirement Index 2015-2016, continues its proud tradition of providing quality care to health seekers from around the world.

From Australia to Kazakhstan, Bangladesh to the United Kingdom, more than 850,000 health travellers sought Malaysian healthcare services in 2015 alone for treatments in cardiology, neurology, orthopaedics, IVF and many others. Malaysia's National Heart Institute (famously known as Institut Jantung Negara (IJN)) is one of Asia's leading centres for the treatment and management of heart diseases, particularly in paediatric cardiology and cardiothoracic care. Malaysia's leading fertility centre has also reported average success rates of up to 65%, exceeding the global average of 50%. Many premier hospitals have also won multiple international awards, in recognition of their commitment to excellence in quality care.

Highly acclaimed, Malaysian private hospitals and healthcare centres hold accreditations from international agencies of repute, such as the Joint Commission International (JCI), Malaysian Society for Quality in Health (MSQH) and other organizations outlined by the International Society for Quality in Healthcare (ISQua).

Stringent regulations for quality and safety by the Ministry of Health Malaysia guarantee that healthcare services dispensed are of the highest standards, benchmarked against the best in the world. Additionally, a single-fee schedule that maintains ceiling rates for treatment fees and mandates the same rates for international and domestic patients ensures that world-class healthcare in Malaysia remains accessible and affordable for everyone who needs it.

Adding to Malaysia's appeal as a globally-preferred healthcare travel destination are the country's many charms: beautiful natural travel attractions, a kaleidoscope of culture & cuisines, alluring shopping haven and ease of communication, where English is widely spoken alongside many other common Asian languages. Our standing as a leading global halal hub where porcine-free medical services such as vaccines provide peace of mind for Muslim health travellers.

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Awards and Accolades

International Medical Travel Journal Medical Travel Awards 2016

- Health and Medical Tourism: Destination of the Year, Malaysia (2015 and 2016)
- Medical Travel Agency of the Year – Highly Commendable: Malaysia Healthcare Travel Council (MHTC)
- International Fertility Clinic
- Best Marketing Initiative

2016 Frost & Sullivan Asia Pacific Healthcare and Tourism Awards

- Asia Pacific Travel Council of the Year – Medical Tourism: Malaysia Healthcare Travel Council (MHTC)
- Asia Pacific Healthcare Service Provider of the Year
- Malaysia Hospital of the Year
- Malaysia Patient Care Hospital of the Year
- Malaysia Growth Excellence Leadership

2016 GHT Consumer Choice Awards

- Cosmetic Surgery & Aesthetics Service Provider of The Year
- Hospital of The Year in Malaysia
- Pediatrics Service Provider of The Year
- Cardiology Service Provider of The Year
- Orthopaedics Service Provider of The Year

International Living's Annual Global Retirement Index 2015 and 2016

- Best country in the world for healthcare

8th Annual World Medical Tourism and Global Healthcare Congress

- 2015 Public Private Partnership Medical Travel Destination of the Year Award

For a full list of our awards and accolades, visit www.mhtc.org.my/global-recognition

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A Day in the Life of a Senior Feasibility Specialist, *Clinical Research Malaysia*

What is a clinical trial feasibility and why is it important?

I believe that Feasibility Studies are the gateway to bringing more clinical trials to Malaysia. It is not only a tool to assess whether a trial is possible in Malaysia but it is also a method to promote that possibility to International companies which may not yet be familiar with Malaysia's capabilities. From a Sponsor's perspective, it is important to conduct feasibility studies before investing on a trial in Malaysia so Sponsors would ultimately decide whether or not to place their trial in Malaysia. Sponsors need to assess a myriad of factors such as timelines, cost effectiveness, challenges foreseen, patient pool and equipment availability before coming to their decision.

What are your job functions as a Senior Feasibility Specialist in CRM?

I handle pre-feasibility enquiries and full feasibility studies besides arranging meetings with Investigators and CROs. I also maintain our internal databases and coordinate the team's efforts in growing the database.

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I handle pre-feasibility enquiries and full feasibility studies besides arranging meetings with Investigators and CROs. I also maintain our internal databases and coordinate the team's efforts in growing the database.

How many are there in the feasibility team and how is work divided between the team?

Currently there are three of us in the team, including myself, under Business Development. We drive feasibility and discuss technical aspects with Investigators and the industry. We accept requests and enquiries across all clinical therapeutic areas, from medical to surgical, from investigational drugs to medical devices. For the 6 major therapeutic areas of clinical trials in Malaysia, we have each been assigned our own areas to oversee in more detail. I oversee Cardiology and Respiratory, Gurinder oversees Haematology and Endrocrinology while Zaihan oversees Oncology and Gastroenterology.

How has the feasibility process in CRM developed over the years?

It has been through a big leap since the early years. In the beginning, a lot of our work was done with Microsoft Office alone. In 2015, we developed an internal system with our vendor which can enable more organized capture of data, which in turn saves time and allows the Feasibility Specialists to take up more projects at a time. We also developed our internal database of Investigators, to map out each therapeutic area available for clinical trials. Our CEO, Dr. Akhmal, saw the important role of feasibility in bringing clinical trials to Malaysia and grew the team to three. With the development of our system in 2015 and the enactment of a new SOP to incorporate that system, CRM saw an increased uptake of full feasibility from 58 in 2013 and 59 in 2014, to 80 full feasibility projects in 2016 (35% growth). The number of CROs and Sponsors engaging CRM for enquiries saw an increase from 16 to 48 companies (300% growth) in 2015, majority of which are international companies.

Can you describe what happens when a feasibility request comes in.

We receive many types of requests, and we generally categorise them into Non Feasibility Enquiries, Pre-feasibility enquiries and Full Feasibility Studies. A Sponsor or CRO would email us an enquiry and we act to achieve the objective of that enquiry. Non-Feasibility enquiries are not related to any particular study or therapeutic area, such as overview on the Malaysian landscape, which companies to contact for indemnity or which CROs a Sponsor can approach for engaging monitoring and startup activities. Pre-feasibility enquiries involve preliminary questions leading up to the decision whether or not to conduct full feasibility studies in Malaysia. These can include Standard of Care, drug registration status, epidemiology and estimated patient pool of a particular therapeutic indication. Full feasibility studies involve approach of individual sites to ascertain interest in a specific study and a more specific patient pool.

For pre-feasibility enquiries, our standard timeline is 1-3 working days for shorter enquiries and 3-5 working days for longer enquiries. For full feasibility, our timeline is 5-7 working days unless otherwise requested by Sponsor or CRO.

How will CRM's complimentary feasibility service benefit sponsors and CROs?

It is a service designed to assist both the Industry (Sponsors/CROs) and Investigators, and improve efficiency and timelines. CRM functions as a one stop center for national feasibility coverage via its centralized service. A centralized service would mean Sponsors and CROs only need to approach one point to have the overall outcome for Malaysia. This means they can save on resources and manpower for following-up on feasibility in Malaysia and focus them into other important operations.

CRM leverages the strengths of a government owned company to conduct feasibility studies such as:

1. Latest knowledge on Malaysian landscape
2. Updated database and wide pool of Investigators to select from
3. Covers approach of all MOH, MOHE and Private hospitals
4. Strong network and rapport with Investigators and Sites
5. Ability to identify ground level needs of Malaysian Sites for trials
6. From barriers noted, ability to identify improvement points for clinical trials in Malaysia
7. And able to highlight these to high level Ministry of Health Officials to drive change from the top level

On top of all that, the service is absolutely complimentary. All the Industry needs to do is shoot us an email.

What do you enjoy most about your job?

Meeting Investigators as well as Industry people! I've met many wonderful people while working here. It's exciting to see the growth of Industry Sponsored Research in Malaysia - how more Investigators are picking up on ISR and how more Sponsors and CROs are bringing their trials to Malaysia. Also to see how CRM is driving change as an organization and improving the ISR landscape in Malaysia.
Personally, I also get a lot of satisfaction from driving a good response from Malaysia for full feasibility studies.

And the most challenging part of your job?

Meeting deadlines given by Sponsors and CRO which are much shorter than our standard timelines. We do receive requests with shorter timelines (sometimes less than 24 hours for a pre-feasibility, or 3 days for a full feasibility study) which we also assist with. However, we are unable to fully utilize our resources within so little time to achieve optimal results. It would be great if a Sponsor or CRO can include CRM near the beginning of a project, rather than nearing the end as this would help to achieve optimal results.

WORKING ABROAD
IN CLINICAL RESEARCH

Ms Shantini Chelliah shared her experience with CRM in her previous role as a Clinical Operations Manager at Novo Nordisk Malaysia and her current role as Project Manager in Princeton, New Jersey, US.

How did you start off in the clinical research industry?

I started off as a CRA in GlaxoSmithKline and then moved to a Clinical Team Lead role in Quintiles before assuming my position as Clinical Research Manager and then Clinical Operations Manager at Novo Nordisk Malaysia. I am now a Project Manager within Clinical Trial Management in Novo Nordisk Inc. in the US.

What does a Clinical Operations Manager do?

Clinical Operations Manager (COM) is responsible for the operations and deliverable of trials, and is the main contact for any general queries and issues with regards to change of regulations governing clinical trial conduct in Malaysia. As a COM, I was also responsible in overseeing the trials selection process, that would ultimately be allocated to Malaysia, ensuring that they can be done in Malaysia, coordinating feedback from various stakeholders in Malaysia, and our HQ. I was also responsible for approving the sites that were selected for our trials, and providing accurate data on utilization of resources for Clinical Trials in Malaysia. I was responsible along with my manager and our HR in the hiring process for clinical team members in Malaysia.

How long have you been in Novo Nordisk before moving to the US to take up the position as Project Manager?

6 years

When told about this offer to move to the US, how did you react?

I was very excited about this opportunity. I had never been to the US before and I have never worked outside of Malaysia, so this was a chance for me to build my career and experience living abroad. As Clinical Trials in the US are managed differently being a much bigger country, I was happy to be able to learn new processes especially in terms of resource management.

What do you enjoy most about your job?

I love being hands on with my projects. I enjoy listing out risks and opportunities and meeting new site staff whenever I have the opportunity. I love to be one step ahead of what ever challenge I may receive! I love travelling as well.

And the most challenging part about your job?

For now, my challenge is to understand and integrate the different roles and how they work together here as we were more lean in Malaysia. Tasks are handled quite differently here than what I am used to. I am learning new things every day, but having a good core understanding of trial management helps. As a former line of business manager, I am trying hard to ease my manager's burden by learning quickly so I can be more independent! My manager and colleagues have been a source of true support in helping me do my best.

What would be your advise to those who are looking at developing their career in the clinical research industry?

Make the most of every opportunity to learn something new. You just never know where it may lead you.

Shantini Chelliah

Project Manager at Novo Nordisk, New Jersey, US

Malaysian Hepatitis C Patients and Activists Speak Out

Reprinted with permission from the Drugs for Neglected Disease initiative

Dr SS Tan and hepatitis C patients Peace James, Rosalyn, and Rashid Bin Hashim speak out about the difficulty to access affordable direct-acting antivirals.

Peace James, 26, is a young musician, who dreams of travelling the world. He was born with thalassemia and needs regular blood transfsions. He was infected with hepatitis C through a blood transfusion when he was a kid. When treated with hepatitis C through a blood transfusion when he was a kid. When treated with interferon his hemoglobin dropped dramatically and he came close to death.

"DAAs are the only hope for him," says Dr SS Tan, a Hepatologist at Hospital Selayang, Batu Caves, Selangor, Malaysia.

To protect his confidentiality, Peace's face is not shown

Dr SS Tan, Head of Hepatology Services, Ministry of Health, Malaysia, and Head of the Department of Hepatology, Hospital Selayang, Batu Caves, Selangor, Malaysia.

"Sofosbuvir has been registered in Malaysia since September 2015 but it is beyond the reach of my patients. It is not available in government hospitals and it is unlikely to be there with the current price tag. As a clinician, it breaks my heart when I am unable to offer my patients such good treatment just because of its exorbitant cost. You should see the shock on my patients' faces when I tell them the price of DAAs."

Rosalyn, 58, is a community leader and former drug user who was diagnosed with hepatitis C over 25 years ago in Kedah, in Northwestern Malaysia. When severe symptoms of the disease began recently, she was given interferon treatment but had to stop when the side effects turned her life into "hell."

"My doctor at the University Malaya Specialist Centre (UMMC) hospital told me there is a magic drug sofosbuvir that treats hepatitis C without any side effects. I don't know if I will get that treatment because there is a long waiting list in the hospital. You need to fulfil a lot of criteria like viral load count, condition of the liver, age, etc for getting that drug. In short, only the most needy will get it," Rosalyn says.

UMMC is one of the hospitals where DNDi's clinical studies will take place in Malaysia.

"I love my community and I don't want people to go through the kind of stigma and discrimination I went through," she says.

Rashid Bin Hashim, a former drug user, an active member of Hepatitis Support Group, Hospital Selayang, Batu Caves, Selangor, Malaysia.

"The majority of hepatitis C patients in Malaysia are from the drug user community and it is difficult for them to have access to hepatitis C treatment, mainly because they don't know their status. Secondly, they don't go to hospitals to avoid facing discrimination and stigma attached with drug users."

Photo credit: Mazlim Husin/DNDi

SIZE MATTERS

Article contributed by Ch'ng Chin Chin.

Chin Chin graduated with a Bachelor of Pharmacy from Universiti Sains Malaysia. She is currently a pharmacist at Penang Hospital and has been with Clinical Research Centre in Penang Hospital since 2013.

Some papers are more likely to be published than others. A main reason for this is the file drawer effect, a type of publication bias where authors are more likely to submit, or editors accept, positive results than negative or inconclusive results.Positive results here refer to findings that are able to reject the null hypothesis.The decision whether a result is "positive" or "negative"depends onits statistical significance which, most of the time, is defined by a p-value of 0.05. A p-value less than0.05 is statistically significant (positive) while a value above 0.05 is not (negative).

So, what is this gatekeeper of a p-value, really?

The p-valueis the probability under a specified statistical model, of obtaining a result, for example the mean difference between two groups, that are as extreme or more than the one observed if no true effect existed in the population. It gives us a measure of the strength of the evidence that a result is not just a likely chance occurrence.

The question we are trying to answer with the p-valueis whether the data we collect appear to be consistent with the null hypothesis or whether it would be unlikely for us to obtain such a data had the null hypothesis been true (inconsistent with the null). In order to answer this question, we would have to calculate a test statistic (which will give us a p-value)(Figure 1) and for this we will have to know the null distribution. For example, a common test we do when we compare means is the Student's t-test in which the test statistic follows a t-distribution under the null hypothesis.

For the purpose of this explanation, we will do a one-sample t-test to find out if the mean knowledge score of student nurses from District X is different from the national average of 74 and assume the standard normal curve for the null distribution. Before we begin we would also have to establish the alpha value (Type I error) to indicate what p-valuecut-off will be accepted as significant. Here we will use the standard = 0.05.

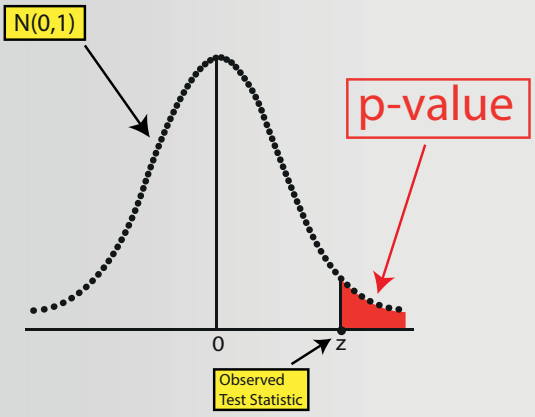

Figure 1

After we have run the tests, we get a test statistic and referring to the null distribution, we want to see where this test statistic is located, whether it is close to the centre of the distribution (consistent with the null) or out in the tail of the distribution (making the null hypothesis less plausible). In other words, the test statistic locates our observation on this distribution to see the extent to which it is an outlier. Say, we get a mean score of 77 from our data and a Z-score test statistics of 1.98, giving a p-valueof 0.048for a two-tailed test. In this case our result is statistically significant as the p-value is less than 0.05 (Figure 2).

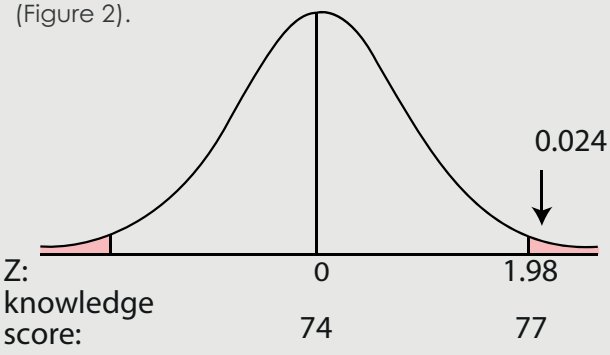

Figure 2

Although a result may be statistically significant, we have to ask ourselves if it is practically significant. In medical research, often we compare different interventions to see if they yield different outcomes. Here, we will have to decide on the effect size that we wish to see, a difference that we would think is clinically significant. For example, if a new hypertension drug is able to lower the blood pressure by an average of 2 mmHg, would we deem the change as clinically significant? Or do we want to see a bigger difference to deem it important? Therefore, we should keep in mind the difference between statistical significance and clinical significance. In a large study, it may be possible to obtain statistical significance for a small magnitude of difference that a smaller study may not detect as significant. To put it extremely, if we were to continue carrying out larger and larger studies, we would eventually be able to detect a statistical significant difference ($p<0.05$) in our outcome of interest, regardless how small.

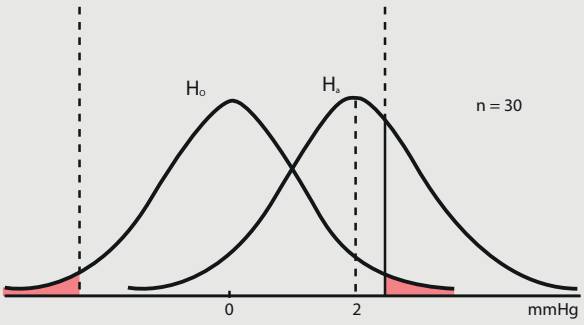

Figure 3A

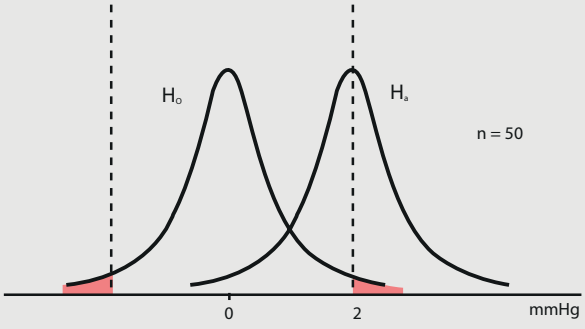

Figure 3B

Take for example Figure 3. The critical values for a significant result are given by the vertical black dashed lines. The critical region ($p<0.05$) is shaded red. If the mean difference (in this case, 2 mmHg) falls outside the dashed lines (Figure 3c), the null hypothesis will be rejected. As we can see from the figure, as the sample size (n) increases, the distribution is less spread out and is more tightly concentrated to its centre. Looking at the null distribution (curve on the left), as n increases the critical values also move closer to 0 together with it until finally in Figure 3c, the mean difference of 2 mmHg falls out of the vertical dashed lines and into the critical region, making it statistically significant. But we have to constantly ask ourselves, although it is statistically significant, is it clinically significant? Is a difference of 2 mmHg clinically important?

The p-value is there to help us avoid using intuition to interpret our data. While the p-value can be a useful statistical measure, it is commonly misused and misinterpreted. We have to keep in mind that the effect size matters and so does the sample size.

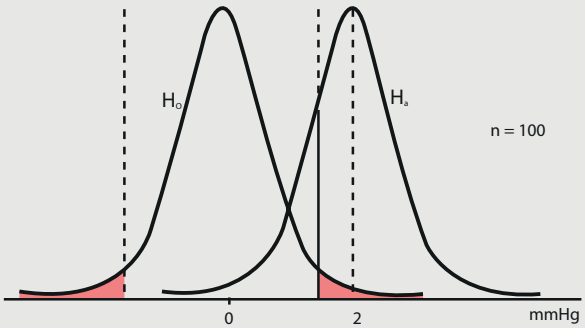

Figure 3C

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 Penang
- International Specialist Eye Centre (ISEC)
- Ipoh Specialist Hospital
- Island Hospital
- Klinik Pakar Au Yong
- Klinik Pakar CN Chin Sdn. Bhd.
- KPJ Ampang Puteri Specialist Hospital
- KPJ KL Hospital
- 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
- Subang Jaya Medical Centre
- Sunway Medical Centre
- Tun Hussein Onn National Eye Hospital
- Yap Psychiatry Specialist Clinic

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

Public Hospitals / Health Clinics (KK)

- Hospital Ampang
- Hospital Bahagia Ulu Kinta
- Hospital Duchess of Kent
- Hospital Kajang
- Hospital Kuala Lumpur
- Hospital Kudat
- Hospital Kota Merudu
- 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 Gunung Rapat
- KK Greentown
- KK Jaya Gading
- KK Jelapang
- KK Karak
- KK Lenggong
- KK Lukut
- KK Pasir Gudang
- KK Putrajaya
- KK Sandakan
- KK Seremban 2
- KK Setapak
- KK Seri Kembangan
- 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

CRM in Photos 2016


8th Sarawak State Health Research Day, 8 - 9 August


9th National Pharmacy R&D Conference, 8 - 10 August


13th MSH Annual Scientific Meeting 2016, 14 - 16 April


DIA 2016 Philadelphia, 26 - 30 June


DIA China 8th Annual Meeting, 15 - 18 May


ESC Congress 2016, Rome, 27 - 31 August


19th Family Medicine Scientific Conference 2016, 10 - 13 August


32nd Annual Congress of Malaysian Society of Nephrology 2016, 29 April - 1 May


50th Malaysia-Singapore Congress of Medicine, 19 - 21 August


DNDi HCV Investigator Meeting, 13 - 14 July


MACT Annual Mini Symposium & AGM, 2 April


DIA Japan - Asian New Drug Conference 2016, 13 - 14 April


Artialis & Université de Liège, Belgium visit to CRM, 17 May


Asia Dengue Conference 2016, 23 - 24 April


Becoming a Clinical Trial Investigator Workshop, 26 April


ISPRM 2016, 29 May - 2 June


Masterclass in Oncology Clinical Trials @ IKN Research Day 2016, 30 August


CRM Plan of Action - Code of Conduct Training, 2 August


CRM Raya Pot Luck, 26 July


CRM visit to Loh Guan Lye Hospital, 22 April


Malaysian Diabetes Educators Society Conference 2016, 22 - 24 April


National Oncology Summit 2016, 22 - 24 April


National Symposium on Ethical Issues in Research 2016, 5 May


Institut Kanser Negara (IKN) Research Day 2016, 30 August


Malaysia Thoracic Society Annual Congress 2016, 28 - 31 July


Meeting Visit to MHTC, 14 June


NCCR 2016 - Big Data Driving Clinical Research for Health, 27 - 28 July


NHAM Annual Scientific Meeting 2016 & CRM Research Workshop, 8 - 10 April


Taisho Pharmaceutical Co. & HOEPharma Holdings Sdn. Bhd. visit to CRM, 13 May


UCSI - International Drug Development Workshop, 6 August


NCCR 2016 Special Event - Venturing into Clinical Research, 28 July


NERCIM 2016/1, 26 May


Servier Visit, 20 July


P1RP - Phase 1 Clinical Trial Guideline Workshop 2, 20 August


P1RP - Phase 1 Clinical Trial Guideline Workshop, 20 - 21 May


UPM GCP Training, 9 August


Prime Site Joint Steering Committee Meeting, 17 August


Penang State Reseach Day 2016, 19 August


Preparing for Regulatory Inspection Workshop,1 August

CRM's Scope of Services

CRM currently provides the following services

FEASIBILITY STUDIES & INVESTIGATOR MATCHING

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

CONSULTATION AND MANAGEMENT OF CLINICAL TRIAL BUDGET

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

REVIEW OF CTA & NDA

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

DEVELOPMENT & PLACEMENT OF STUDY COORDINATORS

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

TRAINING RELATED TO CLINICAL RESEARCH

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

ONE-STOP CENTRE FOR THE INDUSTRY

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

SITES CAPABILITY IMPROVEMENT & ENHANCEMENT

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

IMPROVING PUBLIC AND PATIENT AWARENESS

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

GROWING THE POOL OF INVESTIGATORS AND SITES

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

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

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

CRM
CLINICAL RESEARCH MALAYSIA
Your Global Solutions in One Nation

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

Malaysia is Developing Clinical Research as an Economic Growth Engine

WHY JUST WATCH when you can change tomorrow's healthcare

Find out how the Government of Malaysia supports the clinical research industry through Clinical Research Malaysia.

www.clinicalresearch.my

PhAMA AWARDS 2016

CALL FOR APPLICATIONS!

Theme: Delivering Value with Innovation in the Healthcare Delivery System

Minister of Health Innovation & Research Award

In recent years, the healthcare delivery system in Malaysia is confronted with unprecedented financial pressures. As a consequence, there has never been a greater focus on the need for value-based healthcare quality, outcomes and patient experience. Initiatives and research that demonstrate the potential of health innovations in achieving better patient outcomes, improving patients' quality of life and reducing economic burden of disease are of utmost value. In line with this, the PhAMA Awards 2016 will recognize projects with demonstrable improvement in outcomes, or suggestions and recommendations that could be implemented to support the development of a value-based healthcare delivery system in Malaysia.

Award objective

To celebrate the efforts in innovation and research by individuals or groups with significant contributions to healthcare and/or standards of care in Malaysia.

Prizes

- Grand prize: RM 20,000
- First runner-up: RM 10,000

Who should apply

Healthcare professionals, researchers and students in healthcare sciences from:

- Public/private universities and institutions
- Government/private hospitals and clinics
- Governmental/non-governmental organizations
- Industries

Terms and conditions

- Submissions of projects that are completed, ongoing or in planning stage, from year 2014 onwards are welcomed.
- The project can be conducted individually or as a group effort.
- A regional/multi-country collaborative project is allowed; however, the principal investigator must be a Malaysian citizen and the research must be carried out in Malaysia and beneficial to Malaysians.
- Submissions of projects that are funded by healthcare or pharmaceutical companies are allowed.
- Past submissions from PhAMA Awards 2014 & 2015 are welcomed; however, past PhAMA-awarded submissions will not be accepted.
- All submissions will be thoroughly screened for compliance to theme and criteria. The decision of the panel of judges shall be final and non-appealable.
- Award winners will be announced at the PhAMA Award 2016 ceremony.

About PhAMA

The Pharmaceutical Association of Malaysia (PhAMA) is an association comprising of innovative pharmaceutical companies in Malaysia. Our members are involved in research & development, marketing, distribution, sales, as well as warehousing of pharmaceutical products in Malaysia.

The association serves to build relationships between pharmaceutical companies and other stakeholders of the healthcare sector, namely consumers, healthcare providers, hospital and clinic administrators, the media, regulators and the Government. Our ultimate aim is to ensure access to quality healthcare and healthcare products by all Malaysians. Registered in 1972, our members currently include 41 local and multinational companies. Our members' activities are centred towards providing access to innovative & research-based medicines for a better health and an improved quality of life for all Malaysians.

All submissions shall be made online through: www.phama.org.my on or before 15 September 2016