By Clinical Research Malaysia

CRM bulletin

of Clinical Research and Therapy

ISSUE 13

SPECIAL COVERAGE

Malaysian Phase I Clinical Trial Guidelines

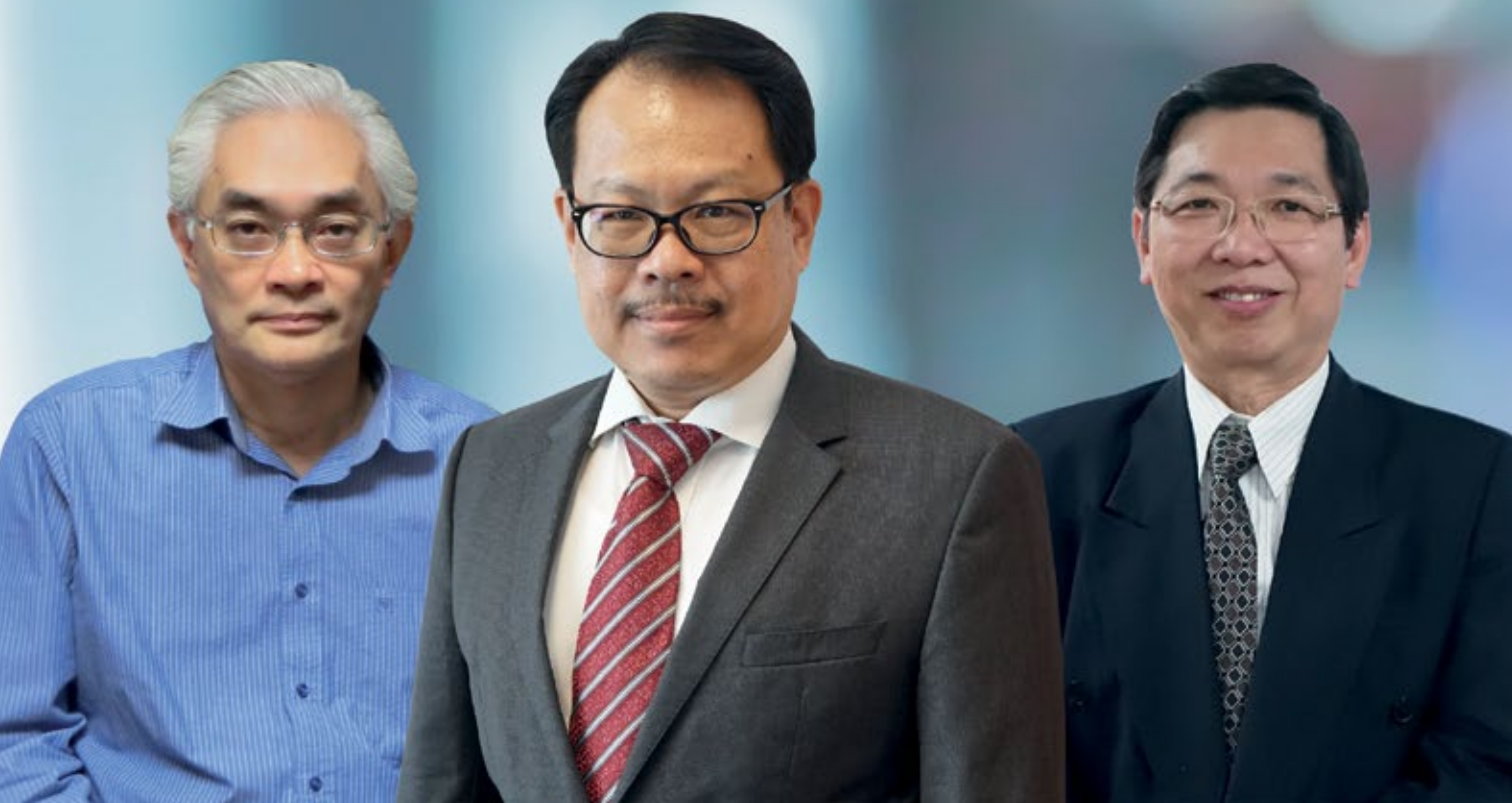
FEATURED SITE

UKMMC Cell Therapy Centre

RESEARCH PERSONALITY

Dato' Dr. Ong Loke Meng
Prof. Dr. Goh Bak Leong
Dr. Wong Hin Seng

INVESTING FOR THE FUTURE OF CLINICAL RESEARCH



ABOUT CLINICAL RESEARCH MALAYSIA

Clinical Research Malaysia (CRM) exists to advance 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. As these studies unfold, we work together with our partners to create an impetus in delivering better treatment to our end consumers, while at the same time creating high-skilled job opportunities.

The strength of our operation lies in our innate understanding of the local clinical research landscape and implementation of international standards. This, when considered in parallel to the fundamental backing of the government ministries, provides us with an incomparable advantage, as we work hand-in-hand with our partners from the nascent stages of development to materialisation of the end product.

In the journey towards a brighter and better future, we facilitate the entry of industry-sponsored research into Malaysia, working closely with the government and relevant authorities to ensure that all regulations and best practices are met.

In CRM, we credit the outstanding performance to the team we have anchored from within our organisation. Their endless pursuit of innovation and continuous improvement have propelled CRM forward to optimise the opportunities that come our way. In tandem with our passion for the clinical research landscape, we ensure core values of transparency, honesty, accountability and trustworthiness resonate throughout CRM. These qualities are also cascaded to our principal investigators and Study Coordinators, who act as the catalysts of the clinical research process.

As CRM vouches for an aspiring future in the clinical research industry, we have implemented mechanisms to expand hospital capacity for clinical trials and tests. This is possible by tapping into our vast talent pool consisting of principal investigators and medical assistants.

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FROM THE CEO's DESK

We step into 2017 with high hopes and expectations for the clinical research industry. Along the way, we have stayed vigilant to ensure that all our plans and strategies are on track. As we approached the end of the year, all I can say is that 2017 has been nothing short of amazing.

A total of 171 industry-sponsored research (ISR) was conducted in Malaysia and 110 MoH sites were recorded to have conducted ISRs. This means that CRM has achieved both of our Key Performance Indicator (KPI) targets for 2017. What is even better is that CRM has achieved two out of three of its KPI set for 2020 under the National Key Economic Area. We have recorded 1055 new and on-going industry-sponsored research (ISR) studies and 1491 jobs created through ISR, ahead by almost 3 years of the 2020 target of 1000 ISR studies and 1000 jobs created in this industry.

I would like to dedicate these accomplishments to all of you who have been working together with us in bringing in ISRs as well as conducting and producing studies of quality and of international standards. I would also like to acknowledge the achievements of our principal investigators, Dato' Dr. Goh Ai Sim and Dr. Lee Li Yuan as well as their study teams who have been recognized by international sponsors and contract research organizations for being the top recruiter in the country and globally. My heartfelt congratulations also goes out to Dr. Voon Pei Jye from Hospital Umum Sarawak who successfully co-authored the FLAURA study which was recently published in the New England Journal of Medicine. Their achievements have definitely put Malaysia on the world map of clinical research.

The coming year will mark more exciting beginnings and challenges as we embark on building a globally trusted organization by working towards ISO 9001:2015 certification, as well as taking up the Malaysian Anti-Corruption Commission (MACC) oath of anti-corruption. CRM will continue working towards making Malaysia the preferred destination for industry-sponsored research and I hope that all parties will continue working together with us to realize this vision for our country.

Contents

Dr. Voon Co-authors the New England Journal of Medicine

SARAWAK, 18 December 2017 – Dr. Voon Pei Jye, the Principal Investigator from Hospital Umum Sarawak, co-authored an article for his FLAURA study which was published on 18 November 2017 in the New England Journal of Medicine recently. His paper on 'Osimertinib in Untreated EGFR-Mutated Advanced Non-Small-Cell Lung Cancer' is a phase 3 trial that showed superior efficacy of osimertinib to that of standard EGFR-TKIs in the first line treatment of EGFR mutation-positive advanced NSCLC, with a similar safety profile and lower rates of serious adverse events.

Hospital Seri Manjung Acknowledged as Highest Recruiter in Malaysia for Vaccine Study

PERAK, 8 December 2017 – Dr. Lee Li Yuan from Hospital Seri Manjung has been appreciated by PAREXEL for his hard work and dedication which has resulted in him being the top enroller for one of the vaccine study. He has constantly recruited according to projections and within timelines. For this vaccine study, Dr. Lee has recruited more than 140%, which is above the recruitment target. In this global vaccine study with 89 sites in 12 countries, Hospital Seri Manjung was the highest recruiter in Malaysia, and ended on 6th place globally. Four Malaysian sites ended in top 13 of all sites globally.

Hospital Pulau Pinang Highest Recruiter Globally for Haematology Study

PENANG, 7 December 2017 – Dato' Dr. Goh Ai Sim and her study team at Hospital Pulau Pinang was recognized by Novo Nordisk as the highest recruiter globally for one of the haematology study despite the various challenges faced during the study period. Overall, 14 countries and 22 sites participated in this study.

The Merdeka Award – Honouring Borneo's Role in Malaria Medical Research

KUALA LUMPUR, 4 December 2017 – This year, the Merdeka Award for Health, Science and Technology was jointly conferred on two extraordinary recipients, Professor Dr Balbir Singh and Dr Timothy William, who were recognised for their pioneering work on the discovery of monkey malaria infecting humans and treatment of the disease respectively.

The ground-breaking research which led to their recognition by the international medical community was carried out right here in Borneo, specifically in the states of Sabah and Sarawak. Fuelled by a passion for research, both Merdeka Award laureates left their old city lives to build new ones.

Professor Balbir and Dr Timothy have each lived in Sarawak and Sabah respectively for more than a decade, devoting themselves not only to understanding malaria better, but to also train a new generation of researchers who share their passion. The impact of Professor Balbir's and Dr Timothy's work is most meaningful right here in Malaysia because our country has the highest incidence of Plasmodium knowlesi cases in the world; knowlesi malaria accounts for over 80% of all malaria cases in Sarawak and Sabah.

Their pioneering work has led to various policy reforms with regards to the treatment and management of malaria patients in Malaysia, all of which have saved many lives. Such was the significance of their findings that the results of their research have already been incorporated into WHO guidelines. While other researchers will carry on and expand on their work in the future, the achievements of Professor Balbir and Dr Timothy are forever immortalised through the Merdeka Award.

Source: Borneo Post Online

NCCR and REACTA Forum 2017

PUTRAJAYA, 27th - 29th September 2017 – The National Conference for Clinical Research (NCCR) is the most prestigious meeting on clinical research in Malaysia. For this year, the NCCR partnered with the REACTA (Regional Asian Clinical Trial Association) in hosting global experts from the USA, United Kingdom, Japan, Korea, Singapore and Malaysia on topics revolving around the theme "Precision Medicine – The Future is Now". The three-day conference was officiated by the Minister of Health, Yang Berhormat Datuk Seri Dr. S. Subramaniam who then went on to launch the Malaysian Medical Research Repository (MyMedR).

This year's CRC Named Lecture was delivered by Professor Dr. Richard Barker, an authority in healthcare and life sciences. By bringing together global experts and thought leaders of the industry, healthcare and academia from various disciplines in research and technology, the conference provided valuable exchanges of scientific and clinical research findings, ideas and best practices in precision medicine.

MoU Signing Between CRM & Taipei Medical University

SARAWAK, 18 December 2017 – A signing of Memorandum of Understanding between Taipei Medical University on behalf of its affiliated hospitals and Clinical Research Malaysia on behalf of Clinical Research Centre, Ministry of Health Malaysia took place at the National Cancer Institute, Putrajaya. The signatories are Prof Shian-Ying Sung (Deputy Director, Taipei Medical University-Joint Clinical Research Centre), Dr Goh Pik Pin (Director Clinical Research Malaysia) and Dr Akhmal Yusof (CEO Clinical Research Malaysia). The MoU seeks for both parties to cooperate to submit, register and execute an investigator initiated study on the efficacy and safety of oral vitamin E (mixed tocotrienol) for 6 months in patients with moderate acute ischaemic stroke.

MoU Signing Between CRM and IMU

KUALA LUMPUR, 23 October 2017 – CRM today signed a Memorandum of Understanding (MoU) with the International Medical University (IMU) that will see both parties collaborating and exchanging industry and academic knowledge. Aligned with CRM's key strategies to grow the number of industry sponsored research, create awareness of CRM and collaborate with stakeholders, this collaboration will bring CRM a notch further in supporting academic institutions like IMU by providing opportunities for its students to be placed at CRM for industrial training. Both parties may also look forward to working closely on research and development activities, including industry product development, using both parties' existing research infrastructure and expertise. The MoU was signed between Prof Abdul Aziz Baba, the Chief Executive Officer & Vice Chancellor of IMU, and Dr. Akhmal Yusof, the Chief Executive Officer of CRM. "We are delighted to sign this memorandum which will enable CRM and IMU to deepen their cooperation on clinical research, improve opportunities for students in industrial training and contribute to building a thriving clinical research ecosystem in Malaysia," said Dr. Akhmal.

CRM Investigator Dialogue 2017

PUTRAJAYA, 25 October 2017 – Fifty-three investigators from 25 Ministry of Health Hospitals, Health Clinics and Universities participated in CRM's Investigator Dialogue, an event which is held biannually to prepare an avenue for investigators to contribute their views and suggestions in growing and accelerating industry-sponsored research in Malaysia. Presentations on patient recruitment campaign, protocol deviations, quality and compliance of clinical trials as well as a talk on Goods and Services Tax (GST) made up part of the programme of the day.

RESEARCH PERSONALITIES

This issue of the bulletin features three prominant research personalities who have made significant contributions in the field of nephrology.

In this section, they share their experiences and views on clinical research in Malaysia.

Prof. Dr. Goh Bak Leong

B.Med.Sc(UKM), MD, MRCP(UK), FRCP(Glasg), FAMM(Mal)

Senior Consultant Nephrologist
Head, Department of Nephrology, Serdang Hospital
Head, Clinical Research Centre, Serdang Hospital

Prof. Dr. Goh is the Head and Senior Consultant Nephrologist in Serdang Hospital. He became a member of the Royal College of Physicians in United Kingdom MRCP(UK) in 1996. He obtained his further training as Renal Fellow at Monash Medical School, Melbourne, Australia. He was awarded the Fellowship of Royal College of Physicians and Surgeons in 2002 and Fellowship of Academy of Medicine of Malaysia in 2012.

Prof. Dr. Goh has published numerous original articles in international peer-reviewed journals in the field of general nephrology, dialysis and transplantation. He has special interest in peritoneal dialysis (PD) and has numerous publications in PD-related articles in Seminars in Dialysis and Peritoneal Dialysis International. Being an ardent speaker in his expertise, he is a frequently sought after invited speakers and has presented numerous scientific papers in international meetings and congresses. He is also involved in many Registries and Clinical Practice Guidelines and sits in many panels / committees / advisory boards as well as professional societies at both national and international levels. Currently, he is the President of the Malaysian Society of Nephrology (MSN), a member of ISPD Working Party on PD Access Guidelines and Asia Pacific Renal Advisory Board member. He is also the Editor of National Renal Registry and was appointed as an Adjunct Professor. He is a member of Asia Pacific Congress of Nephrology 2018, 23rd International Conference on AKI CRRT 2018, and International Society of Nephrology Global Health Summit.

How did you first get into clinical research?

I was first involved in doing research many years ago since I was in Penang Hospital in the early days as a trainee, long before CRC was established. The first time I was properly exposed to the conduct of a clinical trial was in Melbourne, Australia when I was doing my fellowship training at the Monash University. It was in 1998 when my first abstract was accepted in international meeting and eventually published.

When I returned from Melbourne, it was actually the time when CRC had just started to grow. In fact, I was fortunate enough to be the first batch to attend the GCP course conducted by CRC.

My primary interest is still investigator-initiated research (IIR), as it can be seen in most of the works that I have published. When CRM was first conceptualized in 2010, I felt that there was a need to support it. After being involved in many years of research and publication, I find that whenever I encourage junior doctors to do research, they always say that there is not enough time, inadequate resources etc, hence, it is not possible. So, when CRM formally brought in industrial-sponsored research (ISR), I felt that it was a good direction because ISR would be able to bring in the know-how including resources and that the junior doctors can learn from it, and then be on their own to do the IIR later.

How has clinical trials change your practice and management of patient care?

I always believe that a good investigator, a good researcher and a good scientist will always be a good clinician. The first thing is to be a good investigator as they are always very disciplined and paying attention to details. These are also the attributes and traits that are very important to be a good clinician.

The second thing is curiosity. A good researcher is usually the one that is very curious, very inquisitive and also very observant. These are all important attributes which also happen to be important traits of a good clinician.

As a good clinician, our job is mainly to solve patient's problems. I always remind junior colleagues that same diseases can present differently, and different diseases can present the same way. It is very important for one to be aware of that. When one observes certain abnormally or what I call an outlier, to those good clinicians who are very observant, they will start to ask very simple questions. Why did the patient present in this way? Why now and not before? Or why is it that the patient is given the right diagnostic and despite appropriate treatment did not respond as expected? A clinician has to ask these questions which are equally important as a researcher. Therefore, a good researcher would usually become a good clinician.

For example, in my own field, I have many interest areas in research but sometimes due to circumstances, we have to focus in one key area. My niche is in peritoneal dialysis (PD) and I am a key opinion leader (KOL) in peritoneal dialysis in the Asia Pacific region. This is actually circumstantial. What happened was that

many years ago, I observed that PD has always been perceived as second class, inferior technology for patients with end stage renal disease compared to haemodialysis. Based on that observation, I started to ask a very simple question. Why should it be this way?

PD in actual fact has many good scientific reasons to be at least equal, if not better than haemodialysis treatment, but still the pick-up rate is very low. Based on this observation, we started a series of soul searching, root cause analysis and audit, and started a series of research and investigation. And then we realized that the most important factor that hinders utilization of PD is related to the access for dialysis, which is called PD catheter. So, we embarked on a series of research and publication in this area.

Firstly, we demonstrated that if the PD catheter insertion is done by nephrologists with interest in PD, there would be many positive results, not only the outcome would be better, but the response time would also improve. As a result, this finding changed entirely the concept of PD perceived by patients.

Initially we started it in one centre, subsequently we were able to demonstrate that when this same process was replicated in other centres, it produced similar positive impacts of pick-up rate in PD. This was our second paper. The third paper was on how to train the operator and we introduced the concept of CUSUM.

The result of these series of publications has translated into the Clinical Practice Guideline (CPG) on PD catheter insertion by International Society of Peritoneal Dialysis. This has shown that results of research can influence our clinical practice and also translate into good patient care.

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

Sincerity. If I would have to choose just one word to describe a good researcher, I think sincerity is the key. Usually the person who is sincere in carrying out their work would also be a highly- disciplined and honest character. For a good researcher, research integrity is an aspect of moral character. It involves above all, a commitment to intellectual honesty and responsibility for a range of practices that characterise responsible research conduct.

These are all good attributes of a good researcher and these are also important attributes as a good clinician and professional.

However, sincerity is very difficult to measure. It is not measurable.

I always say that the one important attribute for a good worker, if I have to choose just one which is measurable will always be punctuality. When I say punctual, it just does not mean coming to work on time but also one who respects deadlines and not ask for extension. These are usually good and disciplined worker.

A person who is always punctual comes together with many other positive attributes. They are very organised, responsible, disciplined and always deliver what they promised on time which also means they are sincere in their work and are professional.

Prof. Dr. Goh Bak Leong with his team in Nephrology Department

What would be your advice to aspiring clinical researchers?

Research belongs to the field of creative industry. A lot of people think that by doing research, they could become an overnight expert or an overnight celebrity, but unfortunately, research is not like this. For a start, you must have a passion or at least an interest in it. As I mentioned before, a good researcher comes with certain good attributes, they are disciplined, inquisitive and observant. So, to be a good researcher, you should be motivated by your curiosity, as well as the urge and sincere need to find an explanation to your observation and curiosity. That should be the primary motivation of research, not because of anything else, not because of fame or money. I always say that if your aim is about fame and money, it is better to indulge yourself in the reality shows and competitions where you may become sensational overnight.

Research is a very long journey. Just for simple illustration, to come out with a research idea after a good observation, it would take probably no less than 6 months for you to get a protocol ready. If your protocol is so good without any amendment and you manage to get the necessary authorities' approval, you then start the investigator's meeting, start recruiting patients, collecting data, etcetera, the recruitment period itself would take no less than 12 months up to 18 months, or even longer. This will then be followed by data analysis and report which would also take no less than 6 months. So, in total, it would take you about 2½ years, and that is provided that your research is smooth, everything is top notch, and no questions asked. For you to produce your first manuscript which would probably take

another 6 months down the line, or longer which comes to a total of no less than 3 years. If, let us say the manuscript is so well written and gets accepted immediately without any corrections by a peer-reviewed journal and accepted for publication which would require another 6 months, that makes up to 3½ years. This long process is not uncommon. In fact, most of the time, our manuscripts would be revised a couple of times, if not rejected by a few journals. It is not uncommon that from the manuscript stage until it is finally accepted for publication, it could take more than 12 months, or even longer. Therefore, for only one good research, it takes about 3 to 4 years to complete. And you will never become famous with just one publication, because once a paper is published, that paper will be evaluated by your fellow colleagues. They will approve or disapprove your observation, either by critically appraising your paper or repeat your observation. So, for them to cite your work or make reference to your work, it would need another couple of years.

So as a good researcher, you should be motivated by your sincere urge to find the truth. The fuel is your curiosity, the tool is your observation. Eventually, when your work gets recognised, that recognition should be the by-product, bonus, and should not be your primary motivation.

Prof. Dr. Goh Bak Leong with his team in Nephrology Department

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?

To promote a culture of clinical trial, we need to understand the research ecosystem better. First, the most important link is to get the right people. Without the right people, no matter how good your policy is, no matter how developed your infrastructure is, no matter how advance your facility is, no matter how much grants received, human resource, etcetera, it would still not produce a favourable outcome.

So, rather than building more facilities or creating more good policies, I believe that the first approach is to get the right person, identify the key people. Again as I mentioned earlier, researchers belong to the creative industry. Not every single one is cut out to be a reseacher. For example, we have conducted quite a number of GCP courses. How many of them have really been involved in one single clinical trial? My impression is that the number is less than 10%. Worst still, how many of them have become a consistently repeated investigator? That would be probably less than 3%. What does this number mean? Does it mean that we fail in having good policy? Does it mean that we fail in giving them opportunity? I don't think so. I think fundamentally they are probably just not interested to be a researcher or investigator. They probably have many other interest areas which they may excel, but not in this area. So, the support should be built around those who are interested. When you have KOL, usually through KOL, they can provide leadership, they can become a mentor to the junior doctors and over the years, they would build up the whole system together, and subsequently every single one of the team member would eventually become an accomplished researcher in their own right, and then branch out on their own after working so many years with the KOL, and become their own leader in research. The same process would be repeated, and then we would have the multiplying effects.

At the moment, we still do not have the critical mass of good KOL/researcher providing this type of leadership. What we need is to build the support around them, so when we are able to reach the critical mass, the research culture, process and ecosystem would be self-generating eventually.

Dato' Dr. Ong Loke Meng

Consultant Nephrologist, Head of Department of Nephrology and Head of Clinical Research Centre, Hospital Pulau Pinang

Dato' Dr. Ong Loke Meng graduated in 1987 from University Malaya and obtained his membership from the Royal College of Physicians United Kingdom in 1993 and Fellowship of the Royal College of Physicians Edinburgh in 2006. I am nephrologist since 1996 and the head of Clinical Research Centre of Penang Hospital since 2003. I have published 35 papers in peer-reviewed journals.

How did you first got into clinical research?

I received an advanced study coordinator training in 1999 and conducted my first investigator initiated trial comparing two peritoneal dialysis systems in 2000 followed by a randomized clinical trial on lupus nephritis. I conducted the first industry sponsored trial in 2004.

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

Passion. I am passionate about conducting clinical research and teaching clinical research methodology. I firmly belief that medicine cannot progress without research and volunteers are needed to participate in research. However, research needs to be conducted with the highest degree of scientific and ethical standards.

What is your motivation behind conducting clinical trials?

I guess the main motivation for conducting clinical trial is interest. Patients gain access to new therapy that would not otherwise be available to them.

How has the local research landscape evolved over the past decade?

The involvement of CRC and CRM as part of the National Key Economic Area (NKEA) has helped in changing the landscape for clinical trials. Clinical research has certainly gained more prominence nationally and support from administrators has improved because of it.

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

Apart from growth in industry sponsored research, more research should be done in the country to develop medical devices in the country. We also need more high impact research that changes clinical care and public health.

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?

More incentives should be given to companies that conduct clinical research, and also to investigators to participate in research and this includes but not limited to promotions.

RESEARCH PERSONALITY

Dr. Wong Hin Seng

MD; MRCP; M.Med; FRCP(Edin); FAMM

Senior Consultant Nephrologist; Head of Nephrology, Hospital Selayang; Head of Clinical Research Centre (CRC), Hospital Selayang

Dr Wong Hin Seng is a Senior Consultant in Nephrology, Head of Department of Nephrology and Head of the Clinical Research Centre (CRC) in Hospital Selayang. He obtained his Doctor of Medicine (MD) and Master in Medicine (Internal Medicine) from the National University of Malaysia and completed his postgraduate nephrology fellowship in Sheffield Kidney Institute, Sheffield, England in 1997.

He is currently the president of the Malaysian Society of Diagnostic & Interventional Nephrology (MSDIN), president of the Post Graduate Renal Society of Malaysia (PGRSM) and the past president of the Malaysian Society of Nephrology (MSN). He is also the chairman of the Malaysian Organ Sharing System (eMOSS), chief editor of the Malaysian Dialysis and Transplant Registry (MDTR), member of the National Nephrology Credentialing committee, member of the National Renal Registry (NRR) advisory committee, member of the steering committee of the Malaysian Registry of Renal Biopsy (MRRB) and a fellow of the Royal College of Physician of Edinburgh and the Academy of Medicine of Malaysia.

He has over 70 publications, delivered over 150 lectures at scientific meetings both locally and abroad, and presented over 160 research papers in local and international meetings. Dr. Wong has also been a principal investigator for over 20 industry sponsored research. His main focus of interests includes renal transplantation and diagnostic & interventional nephrology.

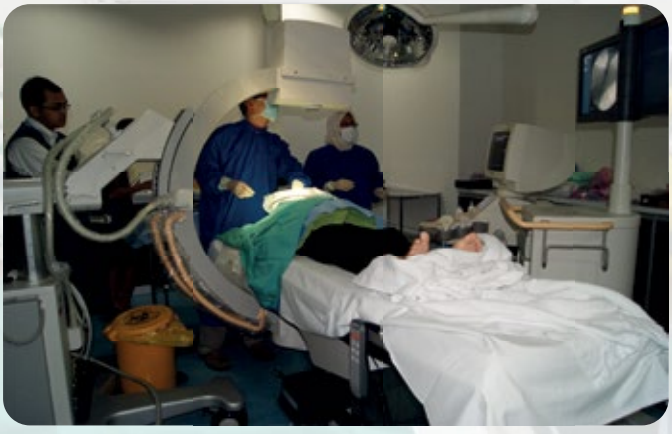
What first sparked your interest in clinical research?

Though I started my first clinical research during my medical school but what sparked my interest in clinical research was during my nephrology fellowship training in the early 1990's where the findings of my clinical study contradicted with what was considered a standard of care and it managed to change our treatment policy.

My first involvement in industry sponsored research (ISR) was in the mid 1990's, which turned out to be a landmark study and that has further increased my passion for clinical research.

How have clinical trials change your practice and management of patient care?

The requirements in conducting high quality clinical trials especially ISR have certainly improved and fine tuned my clinical practice. Having firsthand experience with new compounds during the development phase will provide confidence in using the drug when it is marketed. The ISR experience also enables me to conduct well-designed clinical trials required to improve the care of our patients.



Why should doctors participate in clinical trials?

Participating in clinical trials is essential for every doctor as it will transform one to be a more medically matured and complete doctor. It will certainly change the life of a doctor, making it more interesting, exciting and satisfying. The success in converting my junior doctors to be researchers has been one of the high point in my career.

What are the recent advances made in nephrology clinical research and how will it change the course of treatment in the future?

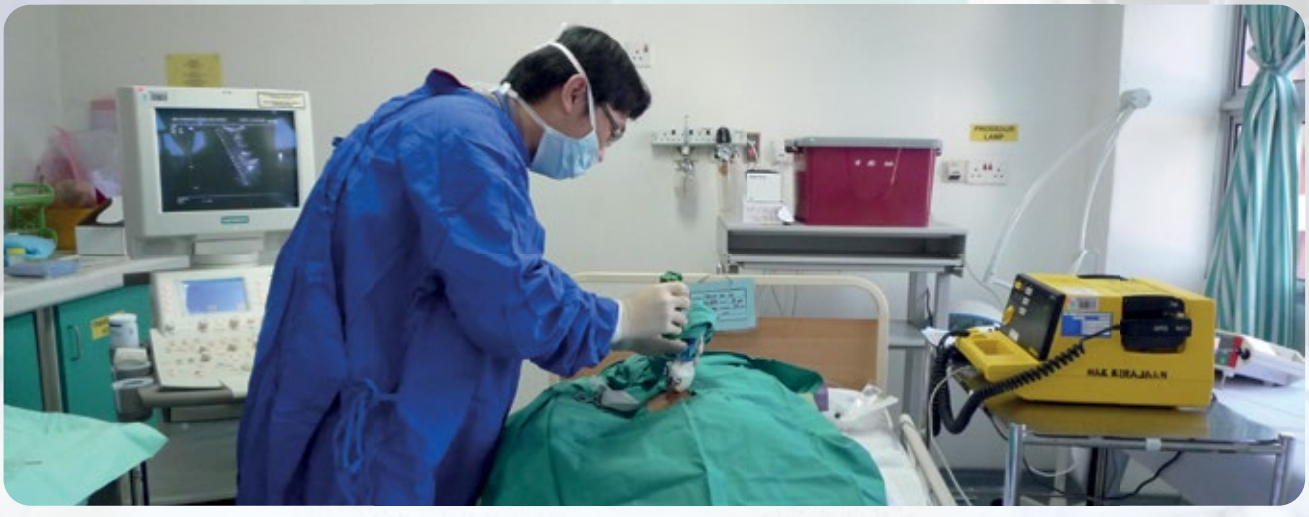
Currently there has been a lot of excitement over the role of hypoxia-inducible factor 1 (HIF-1) in the management of renal anaemia especially its impact on cardiovascular outcome and this will certainly change the way nephrologists manage anaemia in

patients with chronic kidney disease in the future. However what every nephrologist is looking forward to, are advances in the field of diabetic kidney disease, which unfortunately is still lacking.

Do you think that Malaysia has what it takes to be on par with the rest of Asia when it comes to conducting high quality clinical trials? If no, what are we still lacking and what can we leverage on? If yes, what can we do more?

Malaysians are certainly capable of conducting high quality clinical trials. However, we need to establish our reputation in research, and nurture and develop a pool of future investigators who are passionate and well-trained.

I also feel that it is now the right time for Malaysia to develop infrastructures and resources for the conduct of molecular, laboratory and animal research as this is the only way forward.



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MALAYSIAN PHASE I CLINICAL TRIAL GUIDELINES

Endorsed by the
National Committee
for Clinical Research

The shift of industry-sponsored clinical trials to regions like Asia has prompted the Malaysian government to target clinical research, particularly clinical trials, as one of its main economic growth factors. The Malaysian Phase I Clinical Trial Guideline writing committee was therefore set up under the directive of the Malaysian Ministry of Health to develop a standard reference for the conduct of phase I/first-in-human (FIH) trials in the country. The committee members include experts in the field of clinical trials from the Ministry of Health, Ministry of Higher Education and Contract Research Organisations (CROs). In addition, international experts on clinical trials were also invited as Subject Matter Experts and to be part of the steering committee.

> **The current Malaysian Economic Transformation Program (ETP) targets clinical research as one of its main drivers in economic growth. In line with this, the Ministry of Health is focusing on streamlining the processes, expanding its experience, facilities and training in the conduct of Phase I clinical studies.**
>
> ***Dato' Seri Dr. S. Subramaniam, Minister of Health Malaysia***

The development of the Malaysian Phase I Clinical Trial Guidelines marks an important milestone in the history of clinical research in Malaysia. The guideline is part of a much bigger initiative of the Phase 1 Realization Project (P1RP) that aims at establishing and growing an early phase research industry in Malaysia.

This guideline was developed based on the Association of British Pharmaceutical Industry Guidelines for the conduct of Phase I trials (2012 edition), wherein particular sections in the proceeding chapters have been reproduced from the document. Taking into consideration the local regulatory bodies and agencies' existing procedures and the local clinical trial environment, adaptation of relevant areas has been done to facilitate the applicability of these guidelines in Malaysia.

Like many countries within the region, Malaysia is keen to engage with the increasing levels of interest from international sponsors in accessing the untapped clinical trial benefits of Asia. Within Asia, while Malaysia has one of the lowest levels of clinical trial density and levels of per capita government healthcare expenditure; it is also ranked globally within the Top 30 for intellectual property right protection. Together with the Malaysian government's commitment to growing its domestic clinical trials industry, these elements are most definitely increasing Malaysia's attractiveness as a global clinical trial destination for early stage research.

Dr Yooni Kim, Novotech, Executive Director of Asia Operations

Early phase studies play a key role in enhancing the capability of Malaysia in the development of medical science and treatment of diseases. It also helps the pharmaceutical industries gain first-hand experience in ensuring the efficacy and safety of their new drugs. Through the P1RP, a multi-pronged strategy has been developed to create the right ecosystem. Plans are already on way to equip the regulatory agencies with the right knowledge to review Phase I studies that conform to international standards, setting up of a Scientific Review Panel to ensure the rights and safety of clinical trial participants and preparation of sites to conduct these studies. Additionally, a crisis manual has been developed and crisis team trained to manage and mitigate any crisis that may occur during the clinical trial process.

It is hoped that with the development of this guidelines, it will pave the way to Malaysia emerging as a potential, reliable and established Phase I clinical trial destination, in addition to spurring high impact Phase I trials into the country.

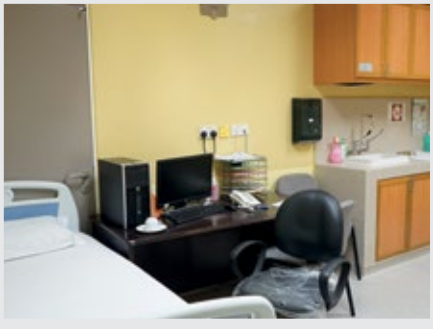
Congratulations to CRM for the successful launch of the guidelines, a culmination of many months of hard work on the part of many.

Professor Datin Dr. Zahurin bt Mohamed,
Department of Pharmacology,
University of Malaya

Visit
www.clinicalresearch.my
to download the guidelines

UKMMC CELL THERAPY CENTRE

Cell Therapy Center is one of the Center of Excellence in UKM Medical Centre (UKMMC) which provides cell-based therapy including hematopoietic stem cells, lymphocytes, dendritic cells, mesenchymal stem cells and mononuclear cells to patients with blood cancers, bone marrow diseases and dengenerative diseases. The Cell Therapy Centre has the aspiration to be among the world leaders in research and development (R&D) of cancer immunotherapy and regenerative medicine.



Cell Therapy Centre, also known as Pusat Terapi Sel (PTS) was established in 1999 with the aim to deliver high quality care using the latest technology and novel treatment modalities to patients with blood cancers and bone marrow failure conditions locally and overseas. Thus far, CTC has conducted more than 200 cases of autologous, allogeneic haematopoietic stem cell transplantations. Our main niche initially consists of hematopoietic stem cell transplantation and cancer Immunotherapy. More recrently, CTC has also widened its scope by developing cell-based therapy to patients with degenerative diseases. PTS works closely with clinical investigators, other research institutes, and various healthcare industries to promote, attract, and facilitate the use of a wide variety of cell-based products. This move is in line with intensive stem cell research and development activities and the increasing market demand for cell-based product.

To ensure that objectives are met, CTC is also actively involved in establishing partnerships with other well established health organizations or institutions.

The services provided in PTS consist of these main components:

1. Hematopoietic Stem Cell Transplantation
2. Regenerative medicine
3. Cancer immunotherapy
4. Novel Drugs Treatment
5. Clinical trial service
6. Stem cell collection and storing

Prof. Dr. S. Fadilah S. Abdul Wahid,
Senior Consultant Haemotologist Clinical & Transport Physician and Head of Cell Theraphy Centre

The center has excellent infrastructure and manpower to support R&D activities related to fundamental and applied research using various types cell-based products. In 2008, CTC has successfully set up a cGMP compliant laboratory in UKMMC in collaboration with InnoBio Diagnostics Sdn. Bhd. This cGMP PTS-IBD Laboratory lab is equipped with a wide range of instruments/tools and managed by a fully trained team. In 2009, the laboratory began its operations in translational research and since then has been producing clinical grade cellular products for regenerative medicine and cancer immunotherapy.

PTS is committed to conduct a high quality clinical trial service by providing a dedicated and qualified personnel consisting of GCP (good clinical practice) certified consultant hematologists and cell transplant physician, clinicians, clinical trial coordinators, clinical research nurses, research officers, and scientific officers.
Since 2011, CTC has successfully conducted many clinical trials in close collaboration with private and public medical institutions abroad and locally.

In the next 3 to 5 years, we hope to extend the indication and scope of cell-based immunotherapy to patients with solid cancers and pediatric populations. We hope that more patients will have access to and benefit from novel and innovative therapy by participating in internationally funded clinical trials. The future and success of cell based therapy for cancers and degenerative diseases in Malaysia require continuing positive input from the regulators, administrators, physicians and scientists.

Poster presented at the NCCR 2017

An Analysis of Industry-Sponsored Research in Malaysia from 2012 – 2016

Ooi A.J.A., Mohd Murad I.M.

CRM CLINICAL RESEARCH MALAYSIA
Your Global Solutions in One Nation

Introduction

There have been significant changes in the growth of the clinical research landscape n Malaysia in the last five years, particularly in industry-sponsored research (ISR). This analysis characterizes and summarizes the various type of ISR conducted in Malaysia between 2012 and 2016.

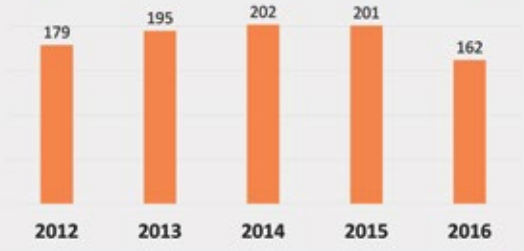
Method

The total number of approved industry-sponsored research in Malaysia between 2012 and 2016 was compiled from all thirteen ethics committees in Malaysia and were characterized according to the types and phases of the trials.

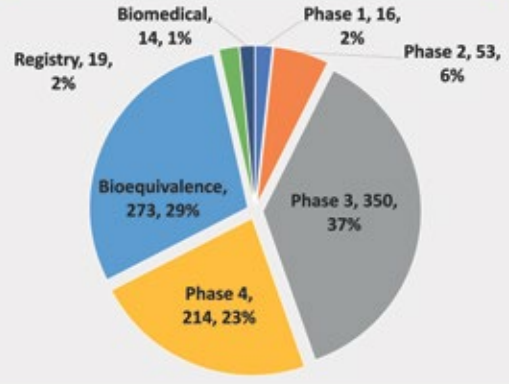
Results

From 2012 to 2016, bioequivalence studies, cardiology, oncology and endocrinology were the top four types of clinical trials conducted in Malaysia. Majority of the trials conducted are in Phase 3 (37%) while a lowest number of trials are in Phase 1 (2%) and biomedical studies (1%). A total of 756 trials were interventional while the remaining 183 were observational studies. From these, 892 were trials on drugs, 33 on medical devices and 14 on biomedical sciences.

Number of Industry-Sponsored Clinical Trials in Malaysia



Industry-Sponsored Trials According to Types & Phases



Clinical Trials According to Therapeutic Area from 2012 – 2016

Types of Clinical Trials

892	33	14
Drug related	Medical Device	Biomedical/Others

Conclusion

The data presented in this report highlights Malaysia's potential in the relevant areas of clinical research and may be a useful source of information for international sponsors and contract research organization looking at conducting industry-sponsored research in Malaysia.

There is ongoing effort by the Ministry of Health in implementing several strategies to create a supportive clinical research ecosystem in the country to attract more ISRs. This include allocating protected time for investigators to conduct clinical research, equipping the sites with the relevant facilities and raising awareness of clinical research amongst healthcare professionals. These initiatives were carried out by a concerted effort of Clinical Research Centre (CRC), the clinical research arm of the MOH, and Clinical Research Malaysia (CRM), a non-profit company established by the MOH that provides speedy and reliable end-to-end clinical research support to trial sites, investigators and the industry.

My personal experience in conducting trials in Sabah and Sarawak

By Soon, Wen Xian

Soon Wen Xian, a medical graduate of Volgograd State Medical University, is currently a Clinical Research Associate at an international pharmaceutical organization based in Malaysia.

When I was a young boy, Sabah and Sarawak have always had an air of mystery about it. Despite both being the largest and second largest state in Malaysia, I never had a chance to visit them. And that was until I joined the clinical research industry.

In 2016, one of the clinical trials which I handled involved two sites from Sarawak, namely Hospital Umum Sarawak and Hospital Miri. The trial is a Phase 2 trial which involves intensive pharmacokinetic (PK) sample collection. The collection can be up to 6 samples within 12 hours in a day. In view of the nature of the trial, the sites are to collect nasal swab and process it with PCR machine to determine its eligibility. Besides this, scheduled on-site visits are very close and each visit requires collection of PK samples, nasal swab and nasal swab samples which subjects did it themselves at home. These arduous procedures were discussed during pre-trial assessment visits and both sites showed very positive attitude in taking up the challenge. Sites were very effective during the submission process to the ethics committee and regulatory agency. All site staff attended the site initiation meetings, trainings were completed on the same day and all signatures were collected on the spot.

L-R: (Front Row) Salina Lisang , Dato' Dr Fam Tem Lom, Dr Desmond Samuel , Matron Teng Leh Hong; (Back Row) DR Lim Sui Xian , Dr Lau Kent Ter, Dr Teh Yeon Chiat

Unfortunately, the sites were opened in December when Christmas, New Year and the Chinese New Year celebrations were around the corner. Malaysia was selected as the rescue site for this trial. To exacerbate the matter, recruitment period was shortened resulting in the sites having only two months to recruit subjects. Once the site was opened, investigators started actively screening for potential subjects and both sites managed to randomize their first subject within 3 weeks.

Dr Chua Hock Hin, Infectious Disease Senior Consultant and Head of Department of Infectious Disease in Hospital Umum Sarawak

Randomization is just the beginning. The next challenge is to ensure that all procedures are done according to the study protocol. At times, patient visits may fall on late nights or on weekends. Investigators and study coordinators stayed back to complete the procedures, nasal swab and PK samples were sent to the central lab, and all data points in electronic data capture system was recorded clearly in the source document. In the end, both sites managed to randomize 4 subjects and screened a total of 12 subjects.

Study team from Hospital Umum Sarawak. From the left, Tan Sia Hong, Sister Tan Hoon Yian, Dr Chan Swee Kim, Chong Tuang Siang

I am very lucky to have these 2 sites as my study site. With the teams effort, the trial ran smoothly. Database lock was also achieved a day earlier compared to planned date and there were no major protocol deviations. After the completion of this trial, both sites received another similar trial. I believe principal investigators play an important role in encouraging participation of other doctors in a clinical trial. The intangible benefits of being involved in a trial is priceless. It is an experience that cannot be obtained through routine clinical care. It gives doctors an opportunity to contribute to the development of new drugs and treatment, besides being exposed to international standards of good clinical practice. It was also a joy to know that the Sub-Investigator of this trial was selected to be the Principal Investigator for a new trial. By having more and more experienced investigators, Malaysia can be one step closer to be the hub for clinical research in this region.

I would like to take this opportunity to thank the teams involved in this trial. Their hard work, commitment and willingness to take up the challenge ensured the successful completion of this trial.

KUALA LUMPUR SPORTS MEDICINE CENTRE (KLSMC) ON STEM CELLS RESEARCH AND THERAPY

Articular Cartilage Repair and Regeneration

Articular cartilage is the soft tissues that surround the bones in the knee joint enabling smooth movement of the knee. Anyone who has suffered or is suffering from damaged cartilage will know just how painful it can be. This can also seriously impact their quality of life and daily function. Regeneration of damaged cartilage has long been thought impossible due to the nature of its tissues. The conventional way of treating cartilage damage often involves complex surgery and is limited to small areas. Even so, the success rates were variable and inconsistent. Often the treatments result in the formation of scar tissues, which cause the cartilage to breakdown faster than normal healthy cartilage; and eventually lead to revision of surgery, higher medical care cost, and little to no improvement in quality of life.

In 2007, Dr Saw Khay Yong from the Kuala Lumpur Sports Medicine Centre (KLSMC) pioneered a technology that can regenerate damaged articular cartilage back to its near-natural state, known as hyaline cartilage. This patented (US 8,377,432 B2) technology combines keyhole 'micro-drilling' surgery and injections of patients' own stem cells coupled with hyaluronic acid into the knee joint. He began his research in animal model with Universiti Putra Malaysia (UPM) in 2005, which concluded that it was possible to improve the quality of repaired cartilage with the application of autologous stem cells (own stem cells). This breakthrough led to a human pilot study in Year 2007 and randomized controlled trial (RCT) in Year 2009. The RCT was partially funded by the Ministry of Science, Technology and Innovation (MOSTI). The clinical results have been published in peer-reviewed journals and received many local and international awards. To date, there have been over 700 success cases of regenerated cartilage under this technology.

In clinical practice, the technology is used to treat cartilage problems that are untreatable anywhere else in the world. The next step to promote the technology is by getting recognition from the United States Food and Drug Administration (US-FDA). Currently, KLSMC Stem Cells (KLSMC-SC), a subsidiary of KLSMC, has received approval from US-FDA to conduct a Phase IIb multi-center clinical trial using this Malaysian innovated technology. The US-FDA trial involves KLSMC, Andrews Research Education Foundation, Florida, and The Department of Orthopaedic Surgery, Stanford University, California. With US-FDA approval, the technology will gain worldwide recognition and put Malaysia on the map for medical excellence.

Dr Saw Khay Yong MB ChB, MCh Orth, FCRS

Consultant Orthopaedic Surgeon, Kuala Lumpur Sports Medicine Centre, Kuala Lumpur, Malaysia

Dr Saw Khay Yong is a Consultant Orthopaedic Surgeon at the Kuala Lumpur Sports Medicine Centre in Kuala Lumpur, Malaysia. He completed his Masters in Orthopaedic Surgery (MCh Orth) at Liverpool University Medical School, UK in 1993. His specialisation in orthopaedic sports medicine includes knee joint arthroscopic surgery with application of stem cells for chondrogenesis together with bone and soft tissue regeneration. He has few patents and multiple publications in the field of peripheral blood stem cells for musculoskeletal regeneration.

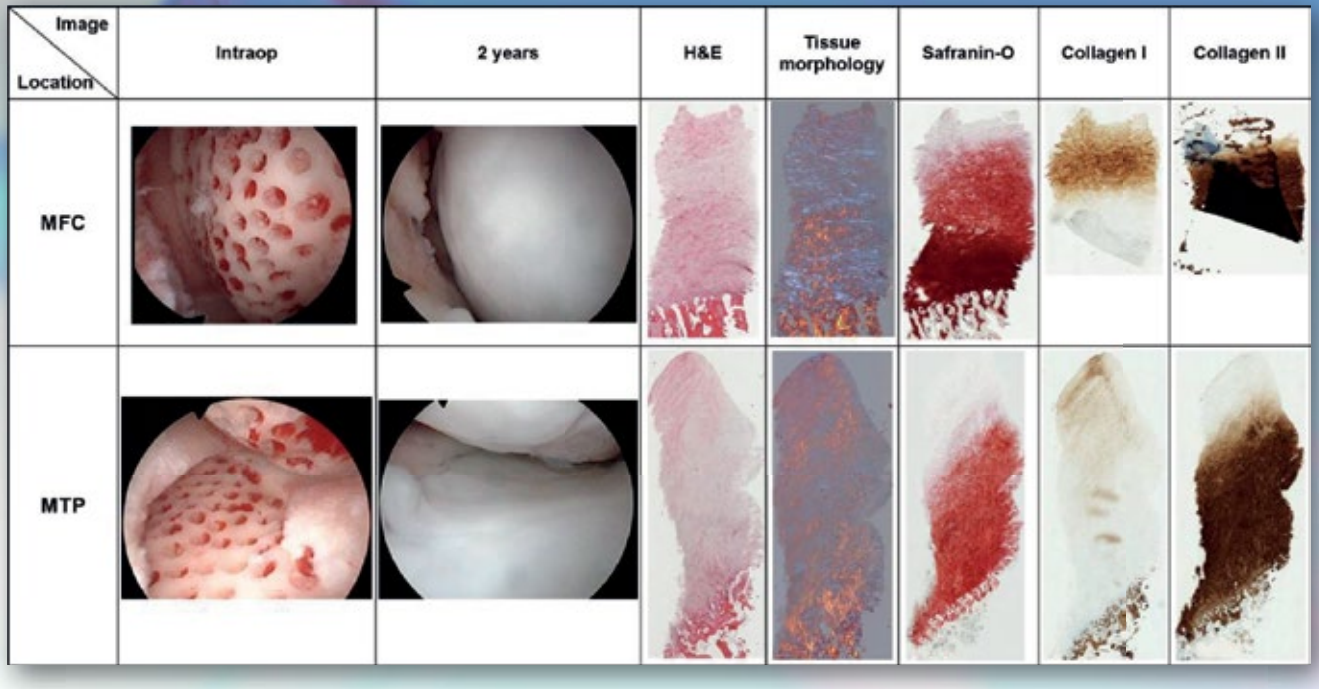


Figure 1. Findings of second-look arthroscopy and histologic assessment of medial femoral condyle (MFC) and medial tibial plateau (MTP) at 2 years in a 49-year-old male patient. Histologic results of regenerated cartilage illustrate resemblance of characteristics to normal articular cartilage, with abundance of proteoglycan and collagen Type II. In addition, when the histologic results were graded using an established histological scoring system, the mean score of regenerated cartilage approaches 95% of the normal articular cartilage biopsy score. The findings show that stem cell therapy with 'micro-drilling' surgery may have the ability to regenerate high-quality cartilage that approaches the normal cartilage in medial-compartment ICRS grade 4 bone-on-bone lesions. (Adapted from Saw et al., 2015)

2017 ROADMAP

HIGHLIGHTS

18 JANUARY

MOU BETWEEN C&R RESEARCH AND CRM

23 FEBRUARY

I AM AWARE CAMPAIGN ACTIVATION AND ROADSHOW

15 MARCH

CRM INDUSTRY DIALOGUE 2017/1

8 APRIL

NHAM-CRM RESEARCH TRACK 2017

16 MAY

CLINICAL TRIALS DAY 2017

28 AUGUST

SCHOLARSHIP AGREEMENT SIGNING BETWEEN CRM, MOH AND NPRA OFFICERS

27-29 SEPTEMBER

NCCR + REACTA FORUM 2017

25 OCTOBER

CRM INVESTIGATOR DIALOGUE

2 NOVEMBER

LAUNCHING OF MALAYSIAN PHASE I CLINICAL TRIAL GUIDELINES

INTELLIM CORPORATION VISIT TO CLINICAL RESEARCH SITES IN MALAYSIA

26 SEPTEMBER

MOU SIGNING BETWEEN CRM AND INTERNATIONAL MEDICAL UNIVERSITY

23 OCTOBER

CRM INDUSTRY DIALOGUE 2017/2

2 NOVEMBER

DR. ALBIRUNI RYAN ABDUL RAZAK VISIT TO PHASE I SITES IN MALAYSIA

11 DECEMBER

CRM
CLINICAL RESEARCH MALAYSIA
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World's First Cambridge-linked Clinical Research Centre in Malaysia

PETALING JAYA: The world's first Cambridge-linked clinical research centre will be set up in Malaysia in partnership with Sunway Group, Sunway Medical Centre and the Jeffrey Cheah Foundation.

Sunway Medical Centre will set up the Sunway Clinical Research Centre to be the regional site partner of the University of Cambridge School of Clinical Medicine.

Researchers from institutions such as Cambridge University, Sunway University and Monash University will be working together in Malaysia to conduct clinical research.

The research will focus on prevention, earlier diagnoses and improved treatments of a range of diseases, suited for the Asian genetic composition.
"With Cambridge's cutting-edge discovery and technology, I hope things can happen fast and certain breakthroughs can be made," he added.

Source: The Stra Online (November 22, 2017)

These Groundbreaking Migraine Prevention Drugs Just Smashed Clinical Trials

A series of late-stage drug trials are showing great promise for a completely new generation of migraine prevention drugs, which could hit the market as early as next year. For the millions of migraine sufferers around the world, this is the most welcome news in decades, as current treatment options are limited and no migraine-specific prevention drugs even existed – until now.

These new drugs are monoclonal antibodies – lab-made proteins of the kind that our immune system deploys to target various substances in the body. In the case of migraine, these antibodies target CGRP (calcitonin gene-related peptide), a molecule known to play a role in migraines.

One of these trials called STRIVE tested injections of the drug erenumab as a preventative for episodic migraine in 955 patients across 121 study sites over the span of six months.

The team found that in their study population of episodic migraines with a baseline of 8.3 attack days per month, erenumab could reduce that number by 3.2 days at a 70-mg dose and by 3.7 days at a higher, 140-mg dose. In the higher-dose group, half of the patients experienced a 50 percent or greater reduction of the mean number of migraine days, which means that from all the days they'd lose to a migraine every month, they got at least half of that precious time back.

Erenumab works by blocking the receptor of CGRP in the brain, and is the only drug to do so. It's being developed by Amgen and Novartis who sponsored the study, and the companies have announced that the FDA has accepted their drug filing earlier this year.

But there are other pharmaceuticals in that race as well. Trial results for a different drug called fremanezumab (developed by Teva Pharmaceuticals) were also published last week – this one was tested in 1,130 chronic migraine patients. When injected quarterly for 12 weeks, the drug achieved a 4.3 day reduction of average headache days from a whopping 13.2 days each month. Unlike erenumab, this drug targets the CGRP molecule itself.

The important takeaway from these trials is that the drugs are definitely performing better than placebo, but researchers acknowledge that more research will be needed to determine whether the medications continue to work and remain safe in the long term.
"Migraine is too often trivialised as just a headache when, in reality, it can be a debilitating, chronic condition that can destroy lives," says Simon Evans from the UK-based charity Migraine Action.

"We hope that this marks the start of real change in how this condition is treated and perceived."

The latest trials were published in the New England Journal of Medicine here and here.

Souce: sciencealert.com (December 4, 2017)

Significant Advances in Treatment of Liver Cancer This Year

KUCHING: This year has seen significant advances in the treatment of Hepatocellular Carcinoma (HCC) also commonly known as liver cancer. Previously, there was only one therapy for advanced stage liver cancer; there are now several alternative therapies available.

According to Prof Pierce KH Chow, senior consultant of the Division of Surgical Oncology, National Cancer Centre Singapore (NCCS), the breakthroughs mean that liver cancer patients now have options to choose from. The results of pivotal clinical trials for three classes of therapies in liver cancer were announced this year, together with major failures as well. The three classes of therapy are immuno-therapy with check-point inhibitor drugs, selective internal radiation therapy (SIRT) and levantinib, a tyrosine kinase inhibitor (TKI). "SIRT offers a higher tumour response, better tolerance with less treatment-related adverse events, and a better quality of life over time than sorafenib. Further analyses will be required to evaluate prognostic factors, cost effectiveness and dose-related efficacy in the SIRT therapy," he stressed.

Liver cancer is the second most common cause of cancer death in the world, but 80 per cent of liver cancer are found in the Asia-Pacific.

Chow, who grew up in Kuching, is instrumental in setting up the clinical trial for liver cancer patients at the Sarawak General Hospital using the 'cutting-edge' treatment of Yttrium-90 Resin Microspheres. Sarawak General Hospital was the first public hospital under the Ministry of Health Malaysia (MOH) in the country to be involved in the trial way back in 2015.

The clinical trial in SGH Kuching was led by Dr Law Chiong Soon, a Nuclear Medicine physician with the collaboration of Hepato-Pancreto-Billary surgeon Nik Azim Nik Abdullah, Interventional radiologist Dr Ahmad Faizal Mohammad Ali and Clinical oncologist Dr Yu Kong Leong.

Source: Borneo Post Online (December 15, 2017)

Pharmaniaga Invests RM 100m on halal, Affordable Vaccines

KUALA LUMPUR: Pharmaniaga Bhd is investing RM100 million in the next five years to make halal and affordable vaccines for local use and export.

This follows Pharmaniaga signing a collaboration agreement with Technology Depository Agency (TDA) and India-based Hilleman Laboratories here today. Under the partnership, Pharmaniaga will establish halal vaccines manufacturing facility here, conduct clinical trials, manage regulatory matters and facilitate products' commercialisation.

"We already have a building in Puchong. We are in the midst of putting the facilities in, which include all the equipment," said Pharmaniaga managing director Datuk Farshila Emran.

"We are hoping to have the facility ready between two to three years from now and start to produce the vaccine," she told reporters at the ceremony.

She said it will take up to five years to commercialise the research by Hilleman Laboratories.

"We are looking produce vaccines for diphtheria and meningitis," she said.

Malaysia's Health Minister Datuk S. Subramaniam officiated at the signing ceremony. Hilleman is a vaccine research organisation in India while TDA is fully owned by Malaysia's Ministry of Finance Inc. Pharmaniaga chairman Tan Sri Lodin Wok Kamaruddin, Hilleman chief executive officer Dr Davinder Gill and TDA chief executive officer Datuk Zailani Safari were present at the event. Subramaniam assures that his ministry is keeping tabs on the vaccine safety while the halal processes will be endorsed by Malaysia's Department of Islamic Development or Jabatan Kemajuan Islam Malaysia (Jakim).

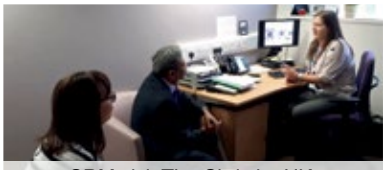
CRM in Photos

A Dialogue Session with the DG of Health Malaysia inLondon, UK, 20 Aug

ESC Congress Barcelona 2017, 26-30 Aug

Scholarship Agreement Signing between CRM, MOH & NPRA Officers, 28 Aug

iMEDITEC 2017, 6-7 Sept

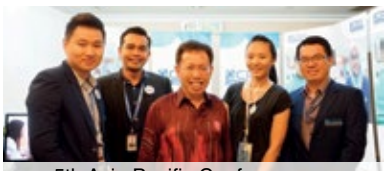


CRM visit The Christie, UK, 7 Sept

Meeting with China Medical University Hospital, 30 Aug

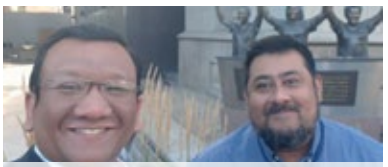
ESMO Congress 2017 I Madrid, Spain, 8-12 Sept

CRM visit Hematogenix Laboratory, Alderley Park, UK, 7 Sept



5th Asia Pacific Conference on Public Health,10-13 Sept

Sabah Research Day 2017, 13 Sept



Visit to Prince Margeret Hospital in Toronto, Canada, 14 Sept

Meeting with MATRADE, 15 Sept

Meeting with delegates from South Korea, 15 Sept

Steering Committee Meeting on the Hep C Program, 20 Sept

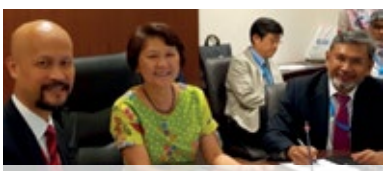
I AM AWARE Roadshow in Hosp. Queen Elizabeth, Kota Kinabalu, 25 Sept

Meeting with FARMASIA Sdn.Bhd., 25 Sept

Meeting with Naluri Hidup Sdn. Bhd., 25 Sept

intellim Corporation visit to Malaysia, 26 Sept

NCCR + REACTA Forum 2017, 27-29 Sept



MoU Signing between CRM & Taipei Medical University, 29 Sept

Negeri Sembilan Research Day 2017, 5 Oct


Visit to intellim Corporation, Japan, 10 Oct

I AM AWARE Roadshow in Hospital Tuanku Ja'afar, 10 Oct

I AM AWARE Roadshow in Hospital Melaka, 11 Oct

I AM AWARE Campus Roadshow in IMU, 13 - 14 Oct.jpg


BioJapan 2017, 11 - 13 Oct


Visit to CROèe, Japan, 10 Oct


Meeting with A-Bio Sdn Bhd, 17 Oct


MoU Signing between CRM and IMU, 23 Oct


CRM Investigator Dialogue 2017, 25 Oct

18th Congress of Asian Society for Vascular Surgery, 26 Oct

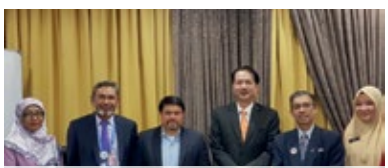
12th MOH-AAM Scientific Meeting 2017, 30 Oct


CRM Industry Dialogue 2017, 2 Nov


Malaysian Phase I Clinical Trial Guidelines Launching, 2 Nov


CRM 2nd Board Meeting for 2017, 1 Nov


College of Physicians, AMM Annual Scientific Meeting, 9 - 12 Nov


Meeting with Hematogenix Lab, 16 Nov


CRM, CRC & IQVIA Prime Sites Network 2nd JSC Meeting for 2017, 15 Nov


Meeting & Visit with Dr Albiruni Ryan Abdul Razak, 27 Nov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CRM
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I AM AWARE
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