BY CLINICAL RESEARCH MALAYSIA

CRM Bulletin

ISSUE 22 | Jul - Dec 2021

REACHING NEW HEIGHTS

RESEARCH PERSONALITY

Dr Lee Li Yuan

FEATURED SITE

Hospital Seri Manjung

SPECIAL COVERAGE

CRM's Phase 1 Realisation Project (P1RP)

RISING STARS IN OPHTHALMOLOGY

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.

CRM
CLINICAL RESEARCH MALAYSIA
Your Global Solutions in One Nation

From The CEO's Desk

Welcome to CRM Bulletin Issue 22!

How time flies, with the end of year 2021. To ensure the safety and wellbeing of our employees, CRM continues to adapt virtual methods into effective action in the conduct of its operations, including study conduct, training, awareness programs and stakeholder engagements. Just in the last quarter of 2021, CRM held its Board of Directors meeting chaired by the Minister of Health, YB Khairy Jamaluddin, conducted its bi-annual industry dialogue and successfully underwent inspection by SIRIM QAS for certification of ISO 37001:2016, Anti-Bribery Management System (ABMS) and re-certification of ISO 9001:2015, Quality Management System (QMS) certification. As an ABMS and QMS certified organization, we strive to be a global trusted organization, delivering studies with speed, quality and reliability.

To further expand Malaysia's capabilities in early phase trials, CRM is committed in growing the country's capacity and expertise in this field. Just in October, Dr Voon Pei Jye has returned from Princess Margaret Cancer Centre, marking the completion of Phase 1 Realization Program by CRM which was initiated in 2016. Besides that, CRM held its first webinar and NPRA Good Submission Practice Workshop both focused on sharing the updates, best practices and experience in the conduct of early phase trials in Malaysia.

Additionally, despite the pandemic, CRM continue to explore more methods in providing speed, reliability and quality in study deliverance. To further expand the scope of end-to-end clinical research support provided by CRM to its stakeholders, CRM had initiated two new services in the second half of 2021, which are Clinical Trial Advertisement service and Study Material Destruction Service. With these services and continued engagement with stakeholders, CRM hopes to create a more viable presence of clinical research foortprint in the industry.

Finally, I'd like to also thank everyone in CRM for striving hard and supporting our clinical researchers and stakeholders, in advancing global health solutions to make Malaysia the preffered destination for sponsored research.

I wish you all safe and well in this unprecedent times, and look forward to making more significant impact to the growing clinical research landscape in 2022.

Dr. Akhmal Yusof
CEO, Clinical Research Malaysia

www.clinicalresearch.my

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HIGHLIGHTS

Nurturing New Talents in Sponsored Research

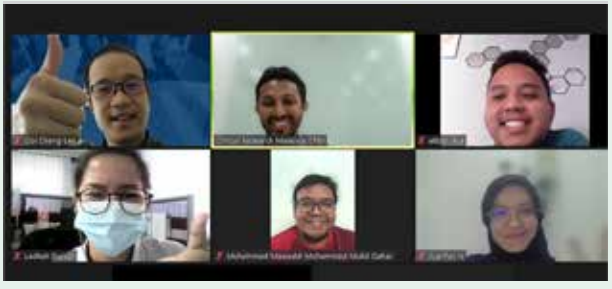
14 July, 30 September & 25 November 2021 – On the second half of the year, CRM successfully conducted 3 Nurturing New Talents in Sponsored Research seminar virtually, driving interest and growing the investigator pool in clinical research.

Asian Pacific Digestive Week 2021

19 - 21 August 2021 – CRM took part as an exhibitor in the Asian Pacific Digestive Week (APDW), a premier annual scientific meeting in Asia Pacific for digestive diseases to showcase Malaysia's capability in the clinical research field of gastroenterology.

Preparation for Regulatory Inspection Workshop

25 August & 24 November 2021 – CRM completed both its workshop on Preparation for Regulatory Inspection in 2021. Led by Mr Oh Chen Wei (NPRA), the workshop shared on the best practices and requirements in regulatory inspection.



Patient Recruitment & Retention Workshop

9 September 2021 – This year's Patient Recruitment & Retention Workshop was successfully conducted in July and November 2021. The main objective of this workshop is to explore how to maximise recruitment approaches by sharing best practices.

GCP Refresher Workshop

15 September & 10 November 2021 – CRM conducted its 3rd and 4th series of GCP refresher workshop, focused on safety reporting (AE/SAE Management), good documentation and site file management respectively, providing a revision on GCP for the study teams and improving knowledge in the management of clinical trial conduct.

Launch of National Vaccine Development Roadmap (PPVN) and Malaysian Genome & Vaccine Institute (MGVI)

1 November 2021 – CRM had the opportunity to network with various local research institutes and local pharma during the launching of National Vaccine Development Plan, an effort to turn the country into a hub for vaccine production and propel the country in local vaccine R&D.

CRM's Board of Directors Meeting

19 November 2021– The CRM's 3rd Board of Directors meeting was chaired by the new Minister of Health, YB Khairy Jamaluddin. During the meeting, the board members were updated on the company's growth and performance as well as sponsored research achievements in Malaysia.

YSN-ASM Chrysalis Awards

23 November 2021 – CRM took part as a mentor, final pitch judge and sponsor for the YSN-ASM Chrysalis Award this year themed "Take Flight: Synergising Science & Technology with Socioeconomic Drivers". The main objective of this program is to recognize and nurture talents of outstanding future researchers in Malaysia, in alignment with the Science, Technology and Innovation (STI) outlook of Malaysia.

CRM is certified with ISO 37001:2016

30 November 2021 – CRM has successfully been certified with the ISO ABMS 37001:2016 certification by the Certification Panel of SIRIM QAS International Sdn Bhd, following its inspection. In addition, CRM also received its re-certification of the ISO QMS 9001:2015.

NPRA Good Submission Practice Workshop

1 December 2021 – CRM together with NPRA conducted the very first NPRA Good Submission Practice Training. Presented by Dr Zaril Harza Zakaria (Head of Evaluation & Safety of Investigational New Product Section), the training was focused on familiarising industry members with processes involved in First In Human CTIL/CTX submission, and to encourage conduct of high potential and impactful First In Human studies in Malaysia.

Industry Dialogue 2021/2

3 December 2021 – CRM have successfully conducted its 2nd Industry Dialogue in 2021 for sponsors and CROs to receive latest updates with regards to the conduct of industry sponsored research (ISR) in Malaysia from the regulatory agencies as well as ethics committee.

Protocol Compliance Workshop

8 December 2021 – CRM completed its 2nd Protocol Compliance Workshop which is aimed to describe on tips in handling and preventing protocol deviation.

International Conference on Drug Discovery & Translational Medicine 2021

8 & 9 December 2021 – CRM took part as an exhibitor and delegate in the International Conference on Drug Discovery & Translational Medicine 2021 (ICDDTM 21) this year. Themed "Advancing Precision Medicine with Emerging Technologies: Bridging Gap Between Academia and Industry", the program is aimed to keep abreast with the recent emergence of innovation technologies in precision medicine.

MoU with Universiti Teknologi MARA

10 December 2021 – CRM entered into a collaborative partnership with UiTM, in establishing and developing an accredited Bioequivalence (BE) Centre at HUiTM Puncak Alam. The centre will include FIH research infrastructure as well, paving the way for more early phase research in Malaysia.

Partnership with Docquity

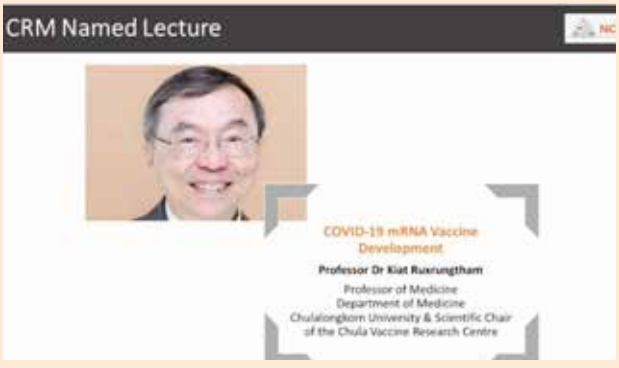
16 December 2021 – CRM has inked a partnership with Docquity, to engage with healthcare professionals on the platform in efforts to further elevate awareness and interest on clinical research in Malaysia. Docquity is Southeast Asia's fastest growing medical education and knowledge sharing platform, exclusively for Doctors.

"CRM is glad to partner with Docquity and to engage with healthcare professionals on the Docquity platform in efforts to further elevate awareness and interest on clinical research in the country."

IN THE NEWS

14th National Conference For Clinical Research

NCCR 2021



18 - 20 August 2021 – The National Conference for Clinical Research (NCCR) is an annual assembly for Malaysia's clinical research industry, during which researchers, industry and regulators gather and share updates on clinical research. In August 2021, the 14th NCCR was held as a three-day virtual conference, organized by Association of Clinical Registries, Malaysia (ACRM) and supported by both the Institute for Clinical Research (ICR) as well as Clinical Research Malaysia (CRM). Revolving around the theme "Niche to Norm", the NCCR 2021 was focused on precision medicine, clinical trials and digital health, and was participated by close to 800 delegates.

Officiated by the Director General of Health, Malaysia, Tan Sri Dato' Seri Dr Noor Hisham Bin Abdullah, the program featured a line-up of named lecture series, plenary and symposium sessions by over 20 international and locally renowned researchers. Among noted session was the CRM Named Lecture by Professor Dr Kiat Ruxrungtham who is the Scientific Chair of the Chula Vaccine Research Centre, Thailand. During his lecture, Professor Dr Kiat shared on the Chula Vaccine Research Centre's progress towards developing its own Covid-19 mRNA vaccine and the established network of partnerships and collaborations that have enabled the progress of the vaccine development.

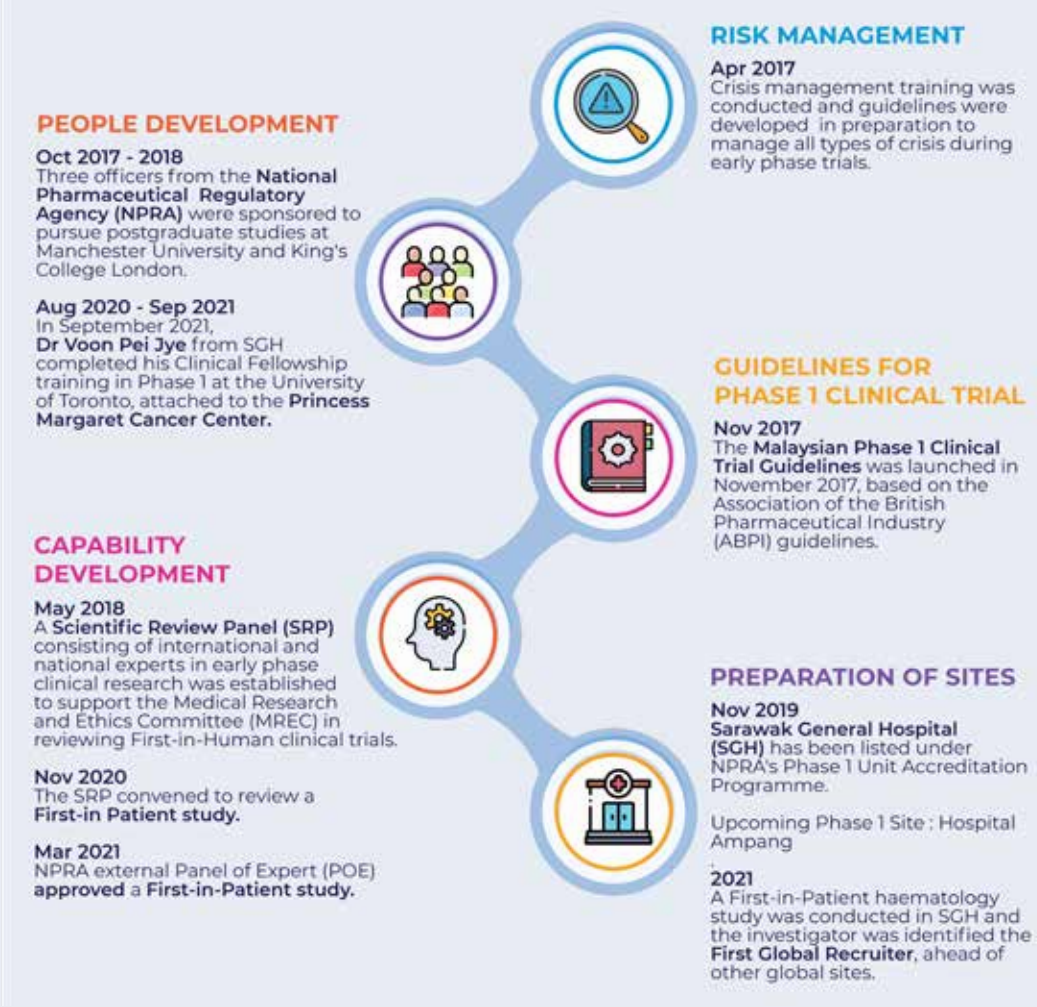
The 14th NCCR conference also featured the annual Wu-Lien Teh Research Awards, marking its seventh collaborative year with the conference. The research awards serve to honor Dr. Wu's legacy and to inspire the new and future generations to conduct research that matters to mankind. Encompassing both the Best Poster Award and Young Investigators Award categories, the conference received 170 e-posters submissions and 6 abstracts were chosen to be presented orally during the conference.

SPECIAL REPORT

Malaysia's Phase 1 Realisation Project (P1RP) Completed!

The Phase I Realization Project (P1RP) was developed by Clinical Research Malaysia in 2016 with the support of Ministry of Health. The objective of its framework is to ensure readiness of Malaysia's clinical research ecosystem for safe and quality conduct of early phase research, especially First-in-Human (FIH)studies. Set as a 5-year plan, CRM is tasked to drive these initiatives which are mainly designed to further enhance Malaysia's capabilities and capacities in FIH. The multifaceted strategy includes the establishment of guidelines for conducting phase I clinical trials in the country, people development, capability development, preparation of sites and risk management.

With the completion of this project in 2021, CRM has further supported the enhancement of FIH capabilities and capacities in Malaysia, by delivering on the needed framework, trained regulators, equipped study site and experienced study team in place.



RESEARCH PERSONALITY

Dr Lee Li Yuan

Consultant Physician & Head of Medical Department, Hospital Seri Manjung

Committee member of Clinical Research Committee, Hospital Seri Manjung

About Dr Lee Li Yuan

Born and brought up in Kampung Koh Sitiawan, Dr Lee is a kampung boy at heart. He went to SRJK UK DIH primary school, and he spent the subsequent 8 years in SMJK NAN HWA. Dr Lee then furthered his study in UM in 1993 and went through his housemanship training in HKL for 1 year. Dr Lee spent the next 4 years in Taiping, before heading back to Seri Manjung Hospital.

Seri Manjung Hospital is a district hospital with specialist care. Dr Lee became the single physician in the Medical Department and subsequently the Head of Medical Department ever since. Dr Lee underwent his GCP training in 2009 and after the establishment of CRC Seri Manjung in 2011, he became the Principal Investigator for the first Industry Sponsored Research (ISR) conducted at Seri Manjung Hospital in 2012.

What motivates you to conduct clinical trials?

Clinical trials are the future of clinical practice. It is interesting to be able to contribute to landmark trials that could change clinical practice. Patients too are able to benefit from investigational products years in advance of time. These trials change the outcomes of patients and markedly improve the quality of life of some.

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

Commitment. The outcomes of the trials do affect the population, and hence these results must not be impacted by any improper conduct of trials. Once committed, investigators must deliver what has been promised. It carries the reputation of the investigator, the site and the nation.

What are the main challenges you have encountered when conducting a clinical trial?

Time and manpower are the two major challenges for me as an investigator. It is important to organise the work schedule properly and to be very familiar with the clinical trial activities so that each visit runs smoothly. Due to this, I often spend time beyond office hours to cater for the work put in.

When it comes to gaining study team members, I often encourage my specialists to join the study as sub-investigators (sub-I). However, as clinical trials last for many years, many leave prior to the trial completion for subspeciality training/ private practices/ to hospital of their choice. There are a few who remained over the past 10 years and among them, three are now principal investigators (PI). Even to date, I continue to enrol new specialists in clinical trial as sub-I, with hopes that they remain and eventually take up the role of PI.

I am fortunate though to have good team members amongst CRM and CRC employees who are the backbone of clinical trials. Without them, I won't have the needed support to conduct clinical trials.

Prior to this, Seri Manjung Hospital was relatively unknown to sponsors / CROs as a trial site, and I thank my team for building the hospital's reputation as recognised trial site by the industry now.

What needs to be changed (e.g.by policymakers/ clinicians) to have Malaysia excelling further in clinical research?

By ensuring adequate and continuity of manpower at site. As many clinicians/ specialists are already burdened by pre-existing clinical duties, it takes a lot of courage for them to decide on taking on clinical research, as this is an added major workload. It is especially more daunting when you are unsure of what is going to happen next week, next month or next year, with some of your team member being transferred with or without any replacement in time. Clinical research workloads should be considered when deploying the resources to a hospital or clinic.

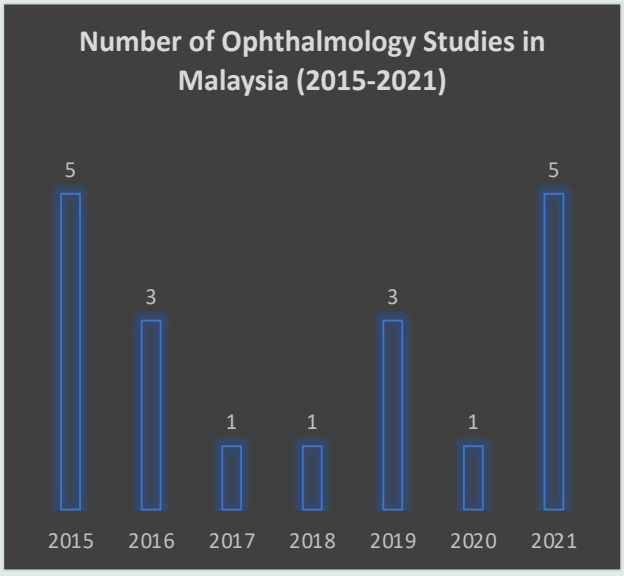
> **"Clinical trials are the future of clinical practice."**

Standing (L-R): Ms. Chiew Shoen Chuen, Dr. Ting Siew Ying, Dr. Chang Meng Lee, Dr. Lee Li Yuan, Dr. Nga Shih Hang, SC Lailye Zuraida Binti Abu Bakar & SC Azirah Binti Osman

Dr Lee Li Yuan in front of CRC, HSM

> **"CRM and CRC staff are the backbone of the trials. I am fortunate to have good team members."**

RISING STARS IN OPHTHALMOLOGY



With over 1800 sponsored trials since 2012, Malaysia has demonstrated capabilities in conducting trials involving various therapeutic areas. In this issue, CRM would like to highlight on opportunities for Ophthalmology trials in Malaysia.

To date, CRM have a total of 171 ophthalmologists registered as investigators, in which 68% are based in public hospitals, followed by 22% in private centers and 10% in university hospitals.

Since 2015, Malaysia has conducted a total of 19 ophthalmology studies, looking into Neuromyelitis Optica, Neovascular age-related macular degeneration & glaucoma conditions. Yet, there is still many opportunities to do more ophtalmology trials in Malaysia, when we study these numbers in comparison to the 2000 opthalmology sponsored trials conducted globally.

Let's hear from our ophthalmologists in Malaysia on their research experience and how we could improve ISR interest in ophthalmology studies in Malaysia.

Dr Fariza Ngah
National Head of Ophthalmology Services

Head of Ophthalmology, Hospital Shah Alam

My first research was in 1996, when I was doing my thesis for my master in Ophthalmology (UKM). It was a Vitamin A deficiency research among the Orang Asli in Perak area in collaboration with the Parasitology team UKM. I stayed in an Orang asli village for almost a week to complete the study. Following that, the study was successfully published in the Asia Pac J Clin Nutr 2002;11(2):88-91.

After completing my master and pursuing my subspeciality training in medical retina and uveitis, I felt as if something is incomplete. We need to know more about patients' disease and should be able to give the best of treatment to our patients. Dato' Dr Goh Pik Pin is one of the few people responsible in introducing and encouraging me to conduct clinical trials. Her dedication and interest in research during her ophthalmology services in Hospital Selayang has opened my eyes and mind on clinical research. The other person is Prof Susan Lightman, my supervisor in Moorfield Eye Hospital, London, who has published thousands of publications from her clinical trials. She has proved that we can become a good doctor and a great researcher at the same time. I started with small scale IIR back in 2004-2006 and I presented my findings during international conferences and made myself known to the 'giant' community of ophthalmology research. It took me another 5 years to actually be involved fully in ISR.

In 2011, Malaysia was invited to be in a global observational study and I was a PI for MOH hospital. We managed to contribute a rather significant number of cases and since then the journey started. To date, I have involved with 5 major ISR study in the field of Ophthalmology. My area of research interest is in Diabetic Retinopathy, age related macular degeneration, retinal hereditary disease as well as uveitis related condition.

My passion for research is basically to give the best of treatment to the patient and optimizing the treatment either preexisting or new treatment which can be affordable and safe for patient. I always believe, one treatment does not fit all, each patient respond differently, therefore we must know different treatment methods for one disease.

Getting involved in clinical trials often keeps the mind and ways of thinking open to the possible outcome of the study. A good study will help me to decide on the management of patients - not all clinical trials can be adopted and used, we must see the outcome/cost effective and safety to the patients.

I would strongly recommend my peers to take up clinical research. Medicine and research are synonyms. We cannot separate between the two. Clinical research will allow you to have cautious mind and not blindly treat patients based on recommendations by others or pharmaceutical companies. Besides, we understand the design of the study/ the statistical analysis correctly done or even the conclusion that is unparallel with the findings. Clinical research also enables us to explore new findings/methods/treatment and meet global researchers and share your opinions, to be known in your field of interest

However, we must not forget patients' safety while doing the clinical trial. Last but not the least, the issue of cost effectiveness will also need to be considered for the products if it is going to be introduced to our population.

Dr Nor Akmal Bahari
Ophthalmologist,
Paediatrics Specialist
—
Hospital Kuala Lumpur

As a physician, I found that clinical trials are essential as it discovers new treatment and intervention for disease. I am interested in building on the latest scientific findings and ensuring novel therapeutic treatments and medications are safe and effectively delivered to patients especially trials related Ophthalmology, particularly pediatrics.

Malaysia is actively developing in clinical trials as more patients are aware about trials now. The standard of patient care becomes more attentive as patient meets the clinician frequently when involved in trials. Participation of patient in trials also contribute to moving science forward and establishing effective new treatments in future. Therefore, patient should participate in trials.

Basically, clinical trials help improve people's life. I would like to engage more in trials which involving pediatrics, as it is actively developing. My aims are to participate in more trials, to introduce new treatment and intervention to improve the quality of patient's life effectively.

INFOGRAPHIC

RECRUITMENT ACHIEVEMENTS IN GLOBAL SPONSORED RESEARCH 2021

Global Top Recruiter | Global 1st Recruiter | APAC Top Recruiter | APAC 1st Recruiter

Non-Small Lung Cell Carcinoma
Dr Fong Chin Heng
Hospital Pulau Pinang

Non-Small Lung Cell Cancer
Dr Muthukkumaran Thiagarajan
Hospital Kuala Lumpur

Pulmonary Hypertension
Dr Geetha Kandavelloo & Dr Martin Wong Ngie Long
Inst. Jantung Negara & Sarawak Heart Centre

Non-Small Lung Cell Cancer
Dr Muthukkumaran Thiagarajan, Dr Lim Chun Sen, Prof How Soon Hin, Dr Soo Hoo Hwoei Fen
Hospital Kuala Lumpur, Hospital Sultan Ismail, Hospital Tengku Ampuan Afzan, Hospital Pulau Pinang

First-in-Patient (Thalassemia/MDS)
Dr Chew Lee Ping
Sarawak General Hospital

Paroxysmal Nocturnal Hemoglobinuria
Dr Veena Selvaratnam
Hospital Ampang

Non-Diabetic CKD
Dr Lee Li Yuan &
Dr Wan Ahmad Hafiz
Hospital Seri Manjung & University Malaya Medical Centre

Non-Small Cell Lung Carcinoma
Dr Hong Fook Yew
Sarawak General Hospital

RSV Infection (Paediatric)
Dr Nga Shih Hang
Hospital Seri Manjung

IgA Nephropathy
Dr Fariz Safhan
Hospital Tengku Ampuan Afzan

Major Depressive Disorder
Dr Wong Kit Chan
Hospital Tuanku Jaafar

Depressive Disorder
Dr Wong Kit Chan
Hospital Tuanku Jaafar

Polycythemia Vera and Elevated Hematocrit
Dr Chew Lee Ping
Sarawak General Hospital

Paroxysmal Nocturnal Hemoglobinuria
Dato' Dr Goh Ai Sim
Hospital Pulau Pinang

Psoriatic Arthritis
Dr Ong Ping Seung
Hospital Raja Permaisuri Bainun

CRM NEW SERVICES

FEATURED SITE

Hospital Seri Manjung

Clinical Departments in HSM:

- Medical Department
- Surgical Department
- Orthopaedic Department
- Obstetrics & Gynaecology Department
- Psychiatric Department
- Outpatient Department
- Ophthalmology Department
- Paediatric Department
- Anaesthetic Department
- Trauma & Emergency Department

Hospital Seri Manjung (HSM) was built in 1994 and is operational since March 1995. Hospital Seri Manjung has a build of 46,088 acre and was built from June 1992 till 30 November 1994 with concept of Turkey Project to replace Hospital Lumut which is located near Lumut Town, approximately 10km from Seri Manjung City. HSM is located in Seri Manjung Town approximatedly 5km from Sitiawan Town, 10km from Lumut Maritime City & 80 km from Ipoh, the Capital City of Perak.

HSM is a referral hospital that provides service to nearby area includes Setiawan, Pengkalan Bahru, Lumut, Beruas, Pangkor, Pantai Remis and Changkat Melintang. According to the projection data by the Department of Statistics, Perak, the total of number of population in Manjung district is 246,700 and the population is estimated to reach 265,500 by the year 2021 (Jab.Statistik Malaysia, 2020).

Total Workforce/ Staff in HSM, including contract personnel – estimated 1,500

Clinical Research Centre, HSM

Operational since 2011, Dr. Nordin Bin Nasir is HSM Hospital Director cum CRC HSM advisor. The CRC Department is headed by Dr Nga Shih Hang since 2018, following his predecessor, Dr Lee Li Yuan. Dr Chang Meng Lee is currently the CRC Deputy Head since 2019, following the forerunner, Dr. Sheila a/p Gopal Krishnan and SN Norsarlizna Bte Mat Sari is the current CRC manager since 2015. There are a total of 4 staff based in CRC HSM consisting of 1 Medical Officer, Dr Ting Siew Ying, 1 Pharmacist; Madam Chiew Shoen Chuen, and 2 CRM study coordinators; Madam Azirah Binti Osman and Madam Lailye Zuraida. CRC HSM has conducted a total of 30 studies to date in various therapeutic area and has achieved numerous recruitment targets ever since.

CRC HSM Facilities



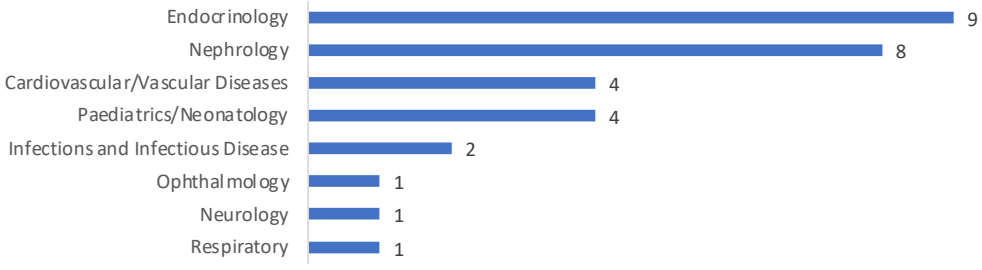



Figure: Number of studies conducted in HSM based on therapeutic areas from 2012 to date

Achievements by HSM

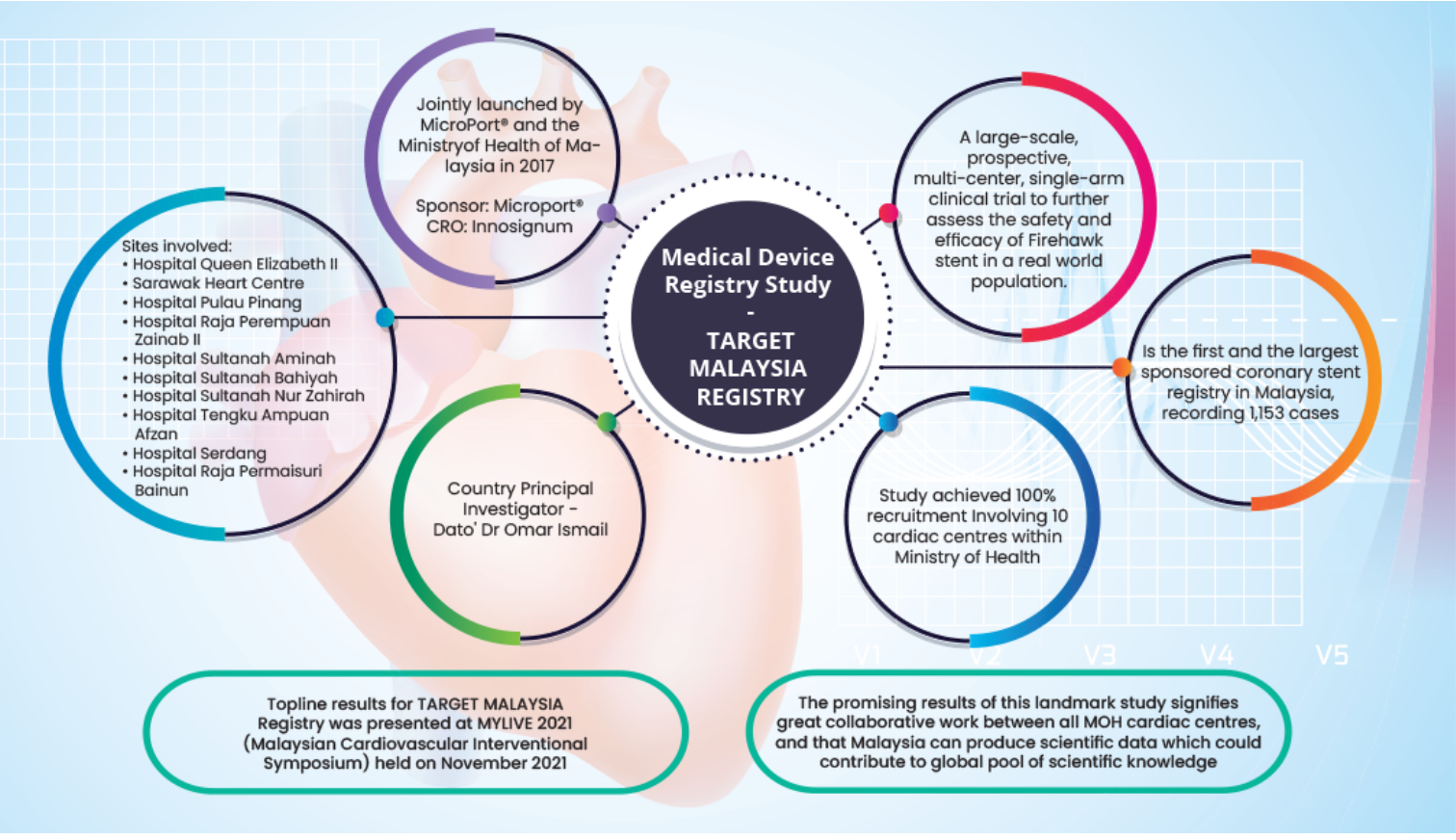
Study	Target	Enrolled	Award/Achievements
MK3102-018 (2013-2016)	30	30	Global Top 12 Recruiter
CARMELINA (2014-2017)	20	37	Malaysia Top Recruiter
NN9924-3790 (2014-2016)	10	12	Malaysia Top Recruiter
VISION (2014-2017)	115	129	Malaysia Top Recruiter and 2nd in Asia Pacific
V118.18 (2016-2018)	190	200	Malaysia top Recruiter
Ascend (2017-2021)	10	23	Malaysia Top Recruiter
TRCA 303 - VALOR CKD	12	21	Asia Pacific Top 5 Recruiter
GXE4KGBio-001 (2020-2021)	8	15	Global Top 10 Recruiter in 2020
ReViral (2021)	2	1	First Global Recruiter
FIND (2021)	8	3	First Country to Achieve Global First Patient Most Enrolled Patients within First Week of Recruitment

Future Plans of Clinical Research Centre, HSM

- To enhance research capacity and capability as well as to contribute towards fulfillment of Ministry of Health requirements
- To develop HSM as one of well-known research institute in Northern Region in Malaysia
- To coordinate more ISR in HSM
- To increase the number of Doctors and Specialists involve in ISR (Approach new investigators)
- More feasibility activities
- Introduce New Sub Investigators (Inexperience) to current active PIs (Experience)
- To introduce ISR and increase involvement by visiting nearby Klinik Kesihatan in Daerah Manjung

REPORT

TARGET Malaysia Registry



On 13th Nov 2021, the topline result of TARGET MALAYSIA Registry was presented at MYLIVE 2021, National Interventional Cardiology meeting. As SEA is an important region of China's 'One Belt, One Road Initiative,' with huge demand for cardiovascular devices, the largest device company In China, Shanghai MicroPort Medical (Group) Co., Ltd. ('MicroPort') has selected Malaysia for this clinical trial. TARGET MALAYSIA Registry is the first Malaysia coronary stent ISR, involving 10 cardiac centres of the MOH with the most robust number of patients recruited. This registry was managed by InnoSignum Sdn Bhd, a local Malaysian, home-grown CRO.

With Dato Dr Omar Ismail as the principal investigator, a total of 1,153 patients were successfully recruited, achieving 100% of recruitment rate with up to 10 cardiac centres of MOH involved in this study. The revolutionary third generation Firehawk is the result of eight years of research and development of MicroPort and it is the world's first and only target eluting stent. As the world's lowest drug dosage coronary stent of 0.30μg/mm^2 Sirolimus at which 90% is released in 90 days, Firehawk combines the merits of the bare metal stent and DES. It adopts unique in-groove abluminal coating design in 86μm Co-Cr stent platform and target-eluting technique with bioabsorbable polymer, which allow Firehawk to achieve the same clinical efficacy with significantly low drug loading, benefiting vascular early healing.

TARGET MALAYSIA Registry has gained positive reassurance from the interventionalist on Firehawk's safety and efficacy. The promising result of this landmark study also shown that all MOH cardiac centres can collaborate to do a major study and Malaysia can produce scientific data that can contribute to global pool of scientific knowledge.

PUBLICATIONS

Impact of COVID-19 on clinical research in Malaysia

Article published in Journal for Clinical Studies, Volume 13, Issue 1, 19 February 2021

By Aina Farhana Binti Zulkipli, Joanne Yeoh, Intan Munirah Binti Mohd Murad, Kalpana Devi A/P Balagangatharan & Nur Ain Binti Amir, Clinical Research Malaysia

Introduction

The catchphrases marking 2020 have been "Stay at home" and "Flatten the curve". The novel coronavirus disease (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-cov-2), has resulted in an unprecedented upheaval for global citizens. Governments across the world have had to battle this surging infectious disease while contending with public health and economic repercussions.

On the 25th of January 2020, Malaysia recorded its first cases of the novel coronavirus disease (COVID-19).[1,2] Up to the 13th of March, the numbers of COVID-19 infections within the country steadily increased until the day after when there was a spike in numbers.[2] Four days later, the Malaysian Government through its National Security Council and under advisement from the Ministry of Health announced the implementation of the Movement Control Order (MCO).[2,3] The objective of the MCO was to curb the spread of COVID-19 as much as possible, preventing the country's healthcare system from crashing under its burden. Enacted under the Prevention and Control of Infectious Disease Act (Act 342) the first phase of MCO only allowed essential services to stay open whilst effectively shutting the rest of the country down.

Impact of COVID-19 on a Global Industry Sponsored Research

The global economies and healthcare sectors are still being greatly impacted due to the COVID-19 pandemic. This tremendous strain also extended to the clinical trial industry. Multiple reports[4–9] agree that the current pandemic has negatively impacted planned and ongoing clinical trials (and research). The major impediments in conducting these studies stem from the challenges posed in managing and assuring the safety of investigators, staff and patients, and managing the sudden diversion of resources towards containment and treatment of the disease.[4–8] Though the United States Food and Drug Administration (USFDA)10 and European Medicines Agency (EMA)[11] developed guidance to support sponsors, investigators and clinical trial management entities during this global public health crisis, various components of ISRs were impacted including poorer patient recruitments, protocol deviations and challenges with monitoring patients in these studies. Table 1 lists some of these challenges in greater detail.

In a survey of 363 clinical trial sites across the globe (including the Asia-Pacific region) 36% were awaiting activation of studies due to the sponsor postponing initiation of recruitment whilst 48% actively enrolling patients faced issues with getting patients in for site visits. Due to this, 34% of these enrolling sites decided to stop seeing patients or moved to virtual visits.6 Of approximately 1000 clinical trial sites being tracked,[5] even as some countries loosen its MCO, there is still delay in initiation of studies and slow enrolment (up by 10% and 13.9% respectively over a 3-week period from June 11th to July 9th 2020). However, studies that suspended enrolment during the more intensive phases of MCO, have shown improvement by a 10% increase. In a larger study by Medidata12 involving enrolment data from >4500 studies and >182,000 sites globally, in March 2020, there was a 65% decrease in new patient enrolment vs. the previous year. The United States of America had a reduction of 67% vs. Japan with a 43% and India with 84% reduction.

Malaysia's industry-sponsored research experience during COVID-19

In recent years, owing to the multiple benefits of developing Malaysia into a clinical trial hub, the Malaysian Government has invested significantly in growing the country's clinical trial capabilities and resources.[13,14] One of its initiatives was the establishment of Clinical Research Malaysia (CRM). Of the many benefits that CRM affords to the robustness of the Malaysian clinical trial ecosystem[13-15] is, as an entity under the Ministry of Health. CRM therefore facilitates ISRs in the country by being a single point of contact between sponsors, CROs, various government agencies and, most importantly, the 36 major clinical research centres nationwide.

The COVID-19 pandemic significantly impacted the conduct of ISRs in Malaysia, akin to that experienced globally. With the implementation of MCO on the 18th of March and the rising withhold patient recruitment and non-essential patient visits. In addition, with the focus on safety of staff and patients in mind, most sponsors and contract research organisations (CROs) either withheld or converted to remote modalities for site start-up visits and monitoring activities which were in line with the USFDA10 and EMA guidance.11 Being the single point of contact, CRM greatly facilitated effective communications between all stake holders, ensuring that all parties were up to date with the latest in the operational status of individual CRM managed trials.

Table 1: How COVID-19 impacts ISR [4,6,8,9]
Reduced prioritisation of ISRs at clinics and hospitals serving as clinical trial sites.
Diversion resources (clinical staff, investigators, space, equipment) at clinical trial sites located in treatment centres (clinics and hospitals)
Non-viable or complete discontinuation of recruitment campaigns.
Increased missed visit due to fear of COVID-19, quarantine measures and travel disruptions causing protocol deviations.
Sudden increase of reportable adverse events (of flu-like symptoms) by patients of ongoing clinical trials.
Non-clinical research staff requiring to work-from-home.
Stay at home orders impacting monitoring of study patients, administration of treatments and data collection.
Possible interruptions to supply of investigational product either from the supplier or to the patients.

Feasibility Studies

One of CRM's key core services is its complimentary feasibility studies.13 During the MCO period, the company decided to withhold outreach of feasibility studies requiring site approaches, except for studies specifically relating to COVID-19. This naturally resulted in a decline in the number of feasibility studies accepted in March 2020 by 46% vs. the previous month. Due to the cordon sanitaire, 14 of on-going feasibility studies recorded during the MCO were put on hold. Understandably, all other on-going studies had timelines extended until the MCO eased into the Conditional MCO (CMCO) and Recovery MCO (RMCO) beginning June 2020. Table 1 shows the number of full feasibility studies from January to June 2020.

CRM's decision to put on hold the feasibility assessments requiring site level information was due to several reasons. Firstly, the Ministry of Health had started building surge capacity in hospitals and as such, some hospitals were specifically designated into COVID-19 treating hospitals, with non-COVID-19 cases being transferred to other nearby hospitals. Secondly, the temporary halt in CRM's feasibility approach was to provide more capacity for clinicians to focus on treating COVID-19 cases that had seen a rise in its number during the MCO in March and April. Thirdly, some of the clinician investigators were deployed to COVID-19 centres to fill the insufficiency of manpower at these sites. Finally, with the restriction of movement being in place, most of CRM Study Coordinators (SCs) worked from home and thus were not able to collect feasibility feedback from the investigators.

The impact of COVID-19 on patient recruitment, protocol deviations, patient visits, and investigational product management

A survey conducted from the 18th March to the 23rd of April 2020 was carried out at all clinical trial sites supported by CRM's SCs across 44 hospitals and institutes to determine the impact of COVID-19 on patient recruitment, protocol deviations, patient visits and IP management. In total, there are 480 active clinical trial sites whereby each trial site may conduct similar study protocol.

Patient recruitment

Medidata (2020) conducted an electronic survey in April 2020 at investigator sites in the United States and Asia. It was reported that 63% of them halted new patient recruitment for ongoing trials16. In a follow up survey done in August 2020, there was a decrease in the number of patient recruitment that was halted (39%)[18]. Another study conducted by the DIA China Digital Health Community (DIA China 2020) in February 2020 among 176 responders, 67% experienced suspension of subject recruitment[17]. Similarly in Malaysia, most of the clinical trial sites located within the Ministry of Health hospitals were closed and research staff including SCs were required to work from home during the MCO.

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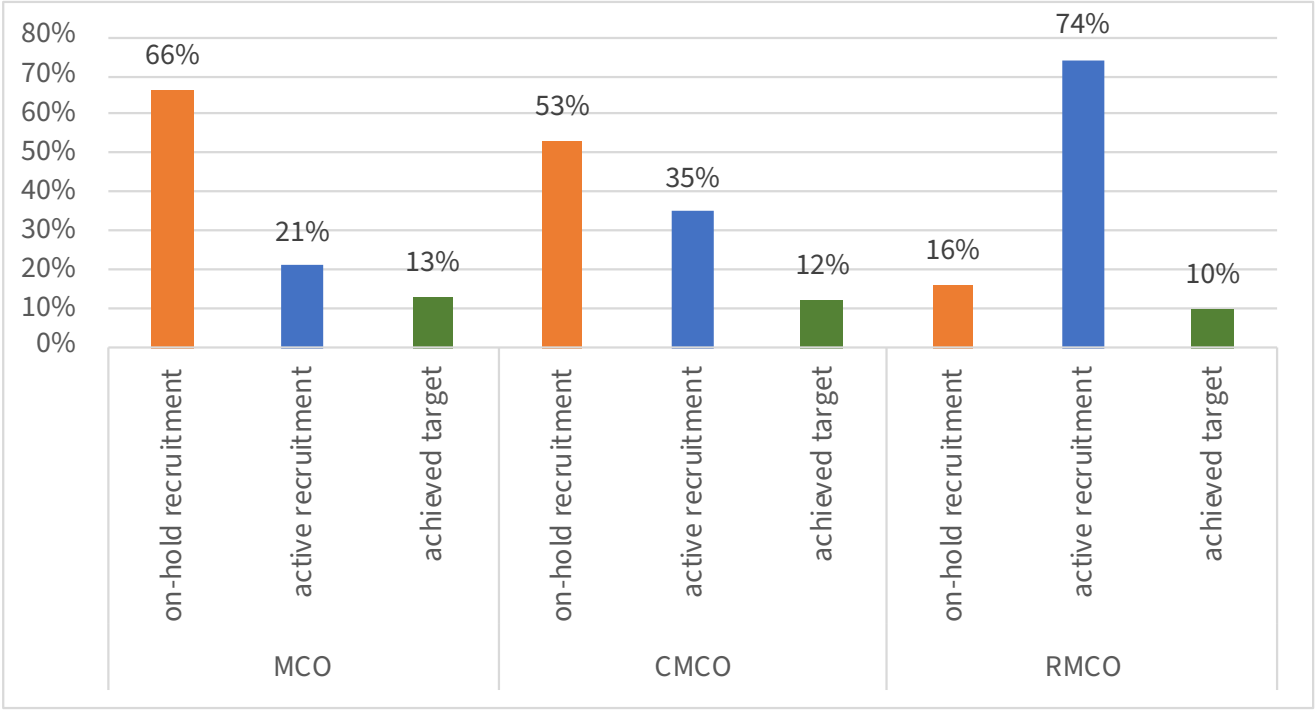
Similarly in Malaysia, most of the clinical trial sites located within the Ministry of Health hospitals were closed and research staff including SCs were required to work from home during the MCO. The impact on patient recruitment is seen in Figure 1. Of the trials managed by CRM, 66% put patient recruitment on hold while 21% maintained active recruitment and 13% had successfully achieved their targets. By June, with the MCO transitioning to CMCO and then to RMCO, patient recruitment resumed.

Trials that withheld recruitment reduced by 13% (from 66% to 53%) and active recruitment increased by 14% (from 21% to 35%). As per another survey conducted from the 1st of July, the percentage of active recruitment increased to 74% with only 16% of trials still withholding recruitment.

These numbers are encouraging and it shows the recovery in Malaysia is very fast. This could be associated with the reducing numbers of COVID-19 cases in the country, the development and implementation of industry specific standard operating procedures (SOPs) as well as, a centralised agency such as CRM effectively bridging communications amongst various stakeholders.

Figure1: Impact of Patient Recruitment



Protocol deviations

As experienced with clinical studies globally, CRM-managed ISRs were faced with protocol deviations (14%). The reasons for protocol deviations are shown in Figure 2, while reasons for protocol deviations classified as “Others” are listed in Table 2. Of the nine protocol deviations classified as “Others”, five were related to the COVID-19 pandemic.

Figure2: Reasons for protocol deviations on clinical studies during MCO

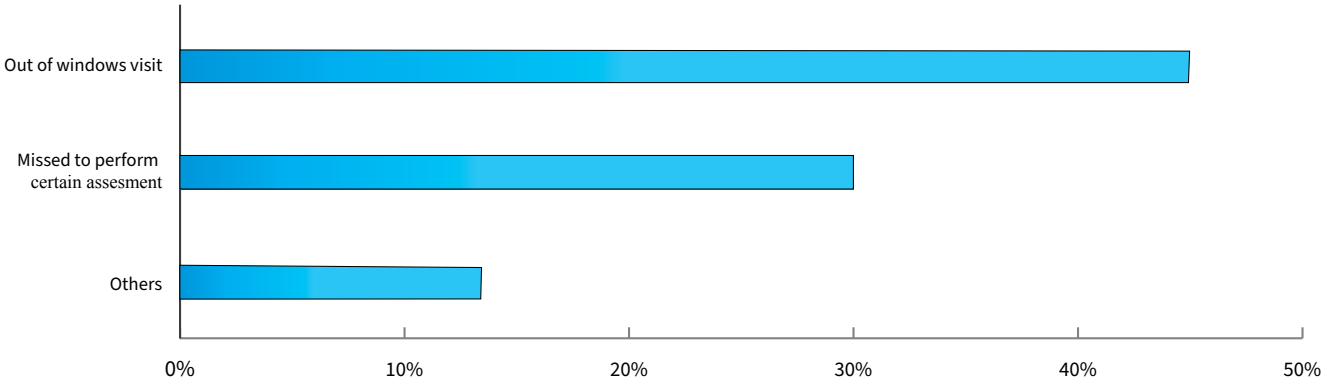


Table 2: Protocol deviations classified as "others"

Related to Covid-19/MCO	- Collected samples unable to be shipped out on the day of visits as per prototcol requirement - Delay in receipt of IP site before end of patient visit window period - Patient visit to site was changed to phone call visits
Not related to Covid-19/ MCO	- IP compliance not within protocol range - Expired kit was used - Temperature excursion of IP storage - Procedures were not performed as per protocol
Protocol deviations occuring in CRM managed clinical trials during the MCOperiod and classified as "Others". Some deviations may have occured more than once during the course of the survey. Of the total CRM managed studies, protocol deviations occured in14%. MCO : movement control order; IP: investigational product.	

Patient visits to trial sites

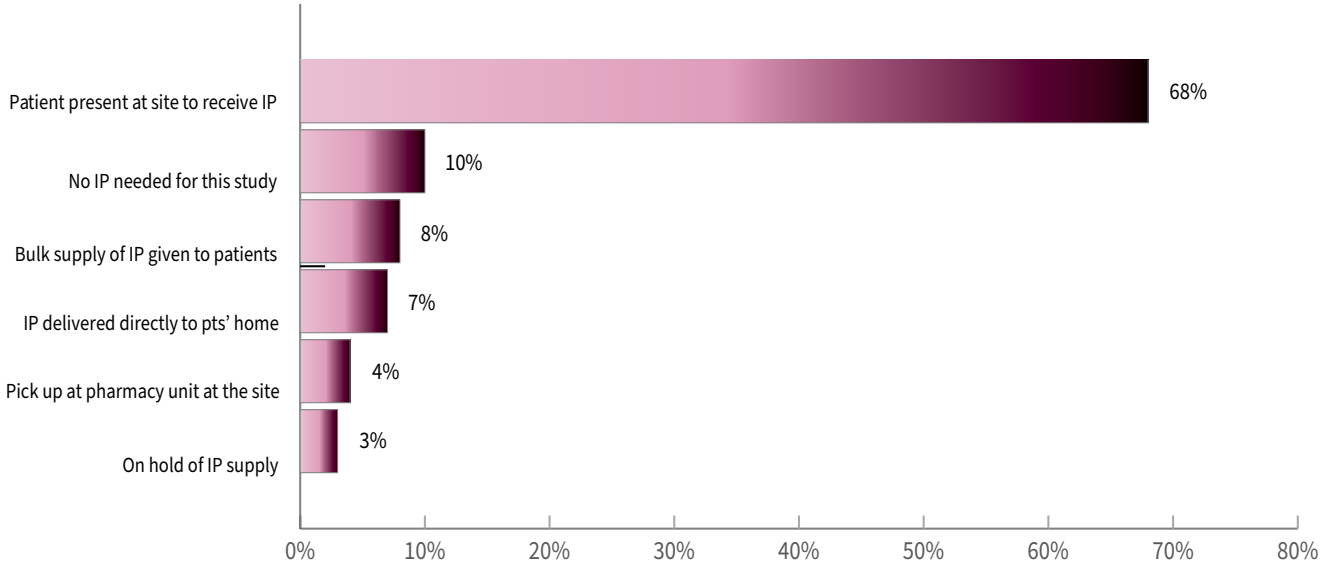
As experienced with clinical studies globally, CRM-managed During the survey period between the 18th of March to 23rd of April 2020 involving 480 studies, 52% (n=247) continued patient visits as per schedule, 39% (n=188) had no active patient visits and 9% (n=45) postponed patient visits. Sixty percent of the 188 trial sites had completed all patient visits before MCO whilst 33% had no patient enrolled yet. Of the 45 trial sites that postponed patient visits, 42% were based on investigator discretion, 23% on sponsor/CRO discretion and 35% due to unwillingness of patient. Throughout the period of March to July, a total of 58 patient visits were reported as cancelled.

Eighty-seven percent of patient visits were done on-site while the remaining 13% follow up visit was done through the telephone/ video call. As patient and staff safety were paramount, SOPs developed by the Ministry of Health were strictly adhered during on-site patient visits. All patients who presented for on-site visits were screened for influenza-like illness symptoms and signs prior to entering the clinics. A specific COVID-19 declaration form was used which, also included travel history.

Investigational product (IP) management

Six percent of trial sites had IP supply withheld from the sponsor. These involved studies in nephrology, cardiology, infectious disease, paediatrics and rheumatology. As for sites that continued to dispense IPs to the patients during the MCO, 68% were dispensed at the sites and if patients couldn't be present on site per the scheduled visit, the IP was either given in advance in bulk (8%) or was delivered directly to the patient's home (7%). Three percent of IPs were "put on hold" for various reasons including safety concerns based on the principal investigator's discretion, IPs which required laboratory results prior to being dispensed and the patient could not be present for these tests and, patient refusing to receive the IP for one month due to suspicion with another disease. No concerns have been reported by site staff and there have not been any reports of adverse effects of withholding the IP in patients. The methods of dispensing the IP in studies is seen in Figure 3.

Figure 3: Methods of IP dispensing in studies during MCO



IP: investigational product; pts': patients. No IP needed= no IP involved is studies (e.g. observational or biomarker studies) or patients have already completed IP prior to MCO

IPs delivered to the patients' homes used locally available courier services. The clinical research associates (CRAs) arranged for courier pick up at the site. Protocols were set in place for IPs requiring temperature control wherein the courier company prepared and sent reports to the SC. In cases of temperature excursions, these were reported to the CRA to confirm if the IP could still be used. The SC also confirmed directly with the patients if the IPs were received in good condition and at the right quantity.

Site monitoring visits

A survey was also done on arrangements of site monitoring visits by the Sponsors/CROs. The findings showed that 54% had monitoring visits postponed, 44% had off-site or remote monitoring and the remaining 2% had no monitoring visits during the MCO period. The majority of sites on off-site or remote monitoring did so via sending scanned documents through email with redacted patient identifiers (80%) and 19% were monitored by tele/video conferencing methods. Of 69 trials slotted to start up, 17% were delayed and 83% continued as planned. Management of site start-ups was done remotely in 58% while 42% had on-site visits. CRM worked together with the hospitals, sponsors and CROs involved in these instances to disseminate correct information to stakeholders in a timely manner to ensure adherence to SOPs that had been developed with specific guidelines and arrangements by individual hospitals. These allowed for planned site selection visits and site initiation visits to be conducted smoothly.

Conclusions

Even with the impact of COVID-19 on ISR's, the Malaysian experience allowed many of the essential clinical studies to carry on with adaptation of processes and few protocol deviations. These included, where possible, converting trial procedures and visits to be performed remotely or on-line. However, a large proportion of studies still followed the traditional route, but did so safely, ensuring that on-site visits were done under strict SOP guidelines with collaboration between the hospital administration, investigators, sponsors and CROs. Though patient recruitment was impacted, our experience showed a fast recovery post MCO. There was also no major disruption of IP supply to patients and the majority were able to visit the site for the IP, largely due to implementation of SOPs.

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Paving the Way for a Robust Research Ethics Review Structure in Malaysia

Article published in Journal for Clinical Studies, Volume 13 Issue 2, 26 April 2021

By Asha Thanabalan from Clinical Research Malaysia, Professor Hans Van Rostenberghe from Universiti Sains Malaysia, Dr Salina Aziz & Dr Lee Keng Yee from Medical Research & Ethics Committee.

Introduction

The foundation of good research is built on sound ethical principles, which require a good rationale, a solid methodology and proper consideration of the important ethical issues that may arise from the research. The main task of research ethics committees is to ensure the above principles, so all research involving human subjects will have an adequate protection of their dignity, rights and safety.

With over 30 years' experience in clinical research, Malaysia has a well-established and experienced ethics and regulatory infrastructure. There are 13 recognised Research Ethics Committees/Institutional Review Boards (RECs/IRBs) in Malaysia, each responsible for the ethical review of research proposals involving human participants conducted at their respective institutions. The Medical Research Ethics Committee (MREC) within the National Institutes of Health (NIH), which is part of the Ministry of Health (MOH) Malaysia, reviews all clinical research protocols involving any of MOH facility.

The majority of public universities and a few private institutions have their own REC/IRB and for institutions that do not have their own REC/IRB, ethics application is sent to any of the recognised RECs/IRBs. In the case of multicenter research proposals, making use of facilities of different institutions, ethical approval is obtained from each of the institutions involved in the research.

In an attempt to increase the capacity and quality of ethical review of research proposals involving humans, and to streamline and harmonise the processes of the various IRB/IECs in Malaysia, the Network of Ethical Review Committees in Malaysia. NERCIM) was established in 2015.

This article aims to lay out the current challenges faced by various research ethics committees in the region, detailing the current Malaysian ethical and review landscape and present NERCIM as a proposed way forward to address these issues.

Challenges faced with research ethics committees in the Asia Pasific Region

While ethics review and all processes involved in it seem to be quite uniformed and harmonised for many of the high-income countries, it is just not feasible to adopt all of their processes especially when factoring in the protection of populations in many low- and middle-income countries in our region. Basic differences in accessibility to health care facilities and drugs are quite notable between countries and even between provinces within many countries. There are also significant gaps in the education, let alone health awareness and commitment to a healthy lifestyle.

On top of the difference in needs between the low- and middle-income countries versus the high income countries, many of the countries in the region still experience a certain lack of capacity to conduct high quality ethical review of complex research proposals, often causing unnecessary delays in the start of international projects and depriving sometimes their institutions of good research opportunities.

Studies of existing research ethics committees (RECs) within different countries across the region pointed out some pertinent issues which are listed in Table 1.1-5 A selection of these issues will be discussed for the Malaysian REC landscape in the next section.

Challenges within research ethics committee frameworks from various countries in the Asia Pasific region [1-5]
Inappropriate composition of committee *Primarily consisting of medical and scientific reviewers* *Experts that may not cover all necessary specialties* *Under presentation from the public (lay persons), legal profession, younger member and/or female population* *Inclusion of administrators in institutional and private hospital committees and, directors/ heads of related departments*
Lack or insufficient expertise on ethical issues
Lack of importance placed in capacity building exercises

Insufficient resources to operate the RECs
Inactive/inconsistent participation of members
Not completely independent especially private and institutional RECs that are funded by their own institution
Lack of standardised standard of operation procedures (SOPs) among the different RECs within a country that leads to variations in practice between institution
Infrequent meetings leading to delays in the overall timelines of clinical trials

Table 1: Various challenges faced by countries within the Asia Pasicfic region involving the structure and operations of research ethics committees.

The current Malaysian REC landscape

Malaysia developed its first Good Clinical Practice (GCP) guidelines in 19996 based on the ICH-GCP as the country prepared to launch itself into the international clinical trial environment. Since then, the country has continuously built up its capabilities, resources and experiences ensuring that Malaysia has a firm footing in the international clinical trial sphere.[5,7,8]

In 2007, MOH issued a directive that requires all RECs/IRBs approving drug-related clinical trials to be registered with National Pharmaceutical Regulatory Agency (NPRA) which is the secretariat of the local Drug Control Authority (DCA).1 The aim was to allow the NPRA to audit and monitor these RECs ensuring that it complied with the Malaysian GCP, regulatory requirements and other established guidelines. The NPRA practices a 3-yearly visit to all recognized RECs/IRBs, including those who applied for first time recognition. They give feedback and demand proper actions before recognition is given and as such they contribute in a major way to the capacity and quality of the ethical review processes in Malaysia.

While most RECs/IRBs in Malaysia tend to have quite a balanced composition in terms of representation of the speciality, gender representation as well as medical, scientific and layperson reviewers, the variety of research projects presented to individual committees is large and not all committees may have enough experts to cover some of the specialised areas and research methods.

While it is not bad to have a decentralized structure of different committees making important decisions for their own institutions and subsequently ensure the post approval processes for their own researchers, harmonization of the review process among the different committees is a desirable aim. A study by See in 2018 showed that even though all recognized RECs/IRBs in Malaysia were compliant to the Malaysian GCP, there was a large variation in referral to other documents in operational procedures, especially with regards to the review process.

Network of Ethical Review Committees in Malaysia (NERCIM): the way forward

In 2013 and 2014 respectively two Malaysian REC/IRB, MREC and the REC of University of Science Malaysia (JEPeM) obtained recognition from FERCAP (Forum for the Ethical Review Committees in the Asian and Western Pacific Region), a voluntary, paid membership organization that was established in the year 2000. FERCAP is a regional forum within the SIDCER (Strategic Initiative for Developing Capacity in Ethical Review) programme and aims to assist and assess the regional RECs compliance to international ethics guidelines and local regulatory requirements. In the process they build up the capacity of their member RECs to deliver good quality ethical reviews.

Existing (2010-2020) strategic objectives of FERCAP include creating a network between different RECs at national, regional and international levels to promote and facilitate training, sharing of common values and goals and, to offer accreditation to RECs by continuous monitoring and evaluation processes.[9]
In 2015, MREC and JEPeM decided to initiate the formation of a Malaysian national network of ethics committees, named NERCIM (Network of Ethics Review Committees in Malaysia), following the examples set by established national networks from the Philippines (Philippine Health Research Ethics Board) and India (Forum for Ethics Review Committees in India), which had achieved successes in harmonization and organization of their own local RECs/IRBs. It was the aim of NERCIM to share the beneficial experiences of getting FERCAP recognition with other committees and to harmonize the review processes (including the post-approval processes) among all REC/IRB in Malaysia.

As an informal network, NERCIM operated with biannual meetings jointly organized by MREC and JEPeM. The meetings consisted of an educational event regarding ethics review of various topics, followed by closed door meetings where common issues and the opportunities for joint educational events and the potential to come up with common guidelines were discussed. Clinical Research Malaysia (CRM), a government body created with the objective of supporting the creation of a robust clinical trial ecosystem in Malaysia, has supported the efforts of NERCIM and has contributed to NERCIM in the planning of the content of the educational meetings and logistics arrangement. NERCIM's

main objective still focuses on capacity building exercises such as providing training and sharing of experiences with an aim for individual local RECs to evolve in their processes to harmonise processes amongst them. While individual RECs can maintain some form of autonomy in their review processes, SOPs according to the format and guidelines of FERCAP have been recommended and the newer RECs have been encouraged to attend training sessions for FERCAP recognition. One of the achievements of the discussion was an informal agreement to expedite reviews of proposals that got already approval from other committees.

NERCIM offers a platform for local FERCAP members to share their experiences and knowledge gained being part of the organisation as, not all RECs in the country have the available resources to become members of the FERCAP. Following the establishment of NERCIM, 2 additional RECs in Malaysia were recognized by FERCAP, joining the likes of MREC and JEPeM.
In the beginning of 2019, the process to formalise NERCIM as an association was undertaken. The concept in forming a registered association comprising RECs across the country, through voluntary application, is to provide an official platform for Malaysian RECs to increase capabilities and facilitate opportunities to overcome current shortcomings. Other than providing training and experience sharing among more established RECs, the platform could guide newer RECs, as more hospitals and universities with medical schools begin to participate in clinical research.

NERCIM members are also discussing the possibility of enhancing collaboration between RECs/ IRBs. A first step, a work in progress at the time of writing this article, is a collaboration between MREC and a university-based IRB. A very good thing would be the establishment of a joint review board with representation of most stakeholders involved for protocols of studies being conducted in MOH and this university's facilities. This would effectively cut short unnecessary time and resources as experienced with current practice.

All drug-related trials conducted in Malaysia require ethics approval from each investigation site involved before a Clinical Trial Import Licence (CTIL) and Clinical Trial Exemption (CTX) is released by the NPRA. If a joint review board could be established, that meets at least once per month, most of the large industry sponsored trials that make use of the facilities of several institutions may be granted approval within a period of 30 to 45 working days, without the need to get approvals from each and every individual REC/IRB. This may make the review process of higher quality, more efficient and more timely.

Conclusion

Through the initial steps initiated by RECs across Malaysia with the formalisation of NERCIM, Malaysia takes another step in its effort to firmly entrench its standing within the international clinical trials environment. Continued efforts to streamline and ensure the adherence to international standards will facilitate and speed up the ethical approval process by all IRB/RECs of the research active institutions. Setting up of a national committee for industry sponsored RCTs seems to be achievable in the long run. It will require a lot discussion and flexibility on the part of all institutions involved.

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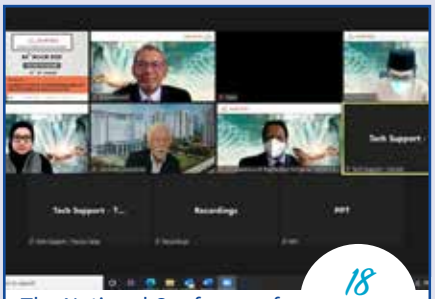
CRM IN PHOTOS

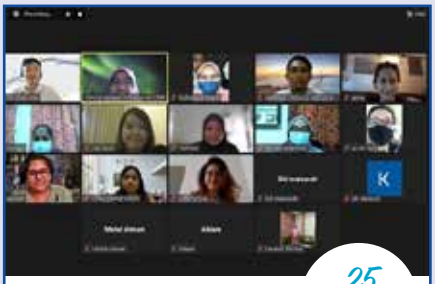
Patient Recruitment & Retention Wokshop

14 Jul



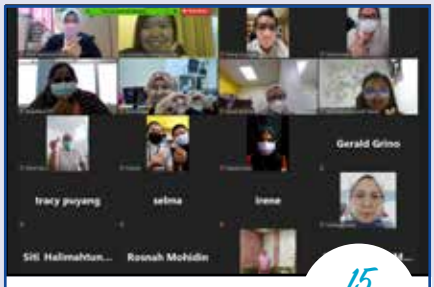
The National Conference for Clinical Research 2021

18 Aug



Preparation for Regulatory Inspection Workshop 2021/1

25 Aug



3rd GCP Refresher Workshop

15 Sep

CRM Webinar: Early Phase Drug Development in Malaysia: Where are we?

21 Oct

Launch of National Vaccine Development Plan at Malaysian Genome Vaccine Institute

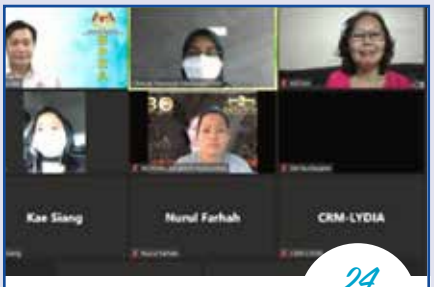
1 Nov

4th GCP Refresher Workshop

10 Nov

3rd BOD Meeting

18 Nov



Preparation for Regulatory Inspection Workshop 2021/2

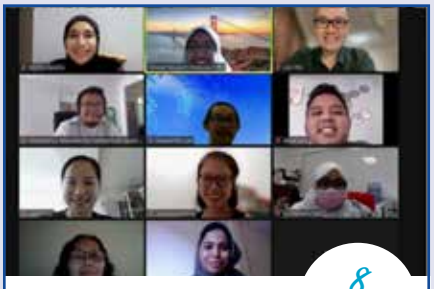
24 Nov

NPRA Good Submission Practice Workshop

1 Dec

Industry Dialogue 2021/2

3 Dec



2nd Protocol Compliance Workshop

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