BY CLINICAL RESEARCH MALAYSIA

CRM BULLETIN

OF CLINICAL RESEARCH AND THERAPY

Issue 20

Special Coverage

Malaysia Sends Its Medical Oncologist to be Trained in One of The Top Cancer Research Centers in the World

Malaysia Partners with Japan's Top Oncology Hospital to Focus on Oncology Drug Development

Featured Site

Hospital Wanita dan Kanak-Kanak Sabah

Rising Stars in Paediatrics

Research Personality: *Professor How Soon Hin*

ACCESS TO INNOVATIVE TREATMENT THROUGH CLINICAL TRIALS

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

Welcome to CRM Bulletin Issue 20!

The year 2020 has ended and activities in Clinical Research Malaysia has been nothing short but abuzz in 2nd half of the year. With the COVID-19 third wave effecting Malaysia at an unforeseen number, we continue to explore more virtual methods and working remotely to provide deliverance of speed, reliability, and quality in study conduct. Just in November, we have hosted a CRM board meeting, audited remotely by the SIRIM team (as part of the surveillance inspection for the continual of ISO 9001:2015 certification), and organized/ conducted online training programs for our investigators as well as industry stakeholders. As one of our initiatives this year, we have also started our journey towards compliance to ISO 37001:2016 Anti Bribery Management System, committed to be a globally trusted organization with integrity and ethical conduct. A briefing session has been conducted companywide to ensure successful implementation throughout the organization.

Many exciting things are happening to the further expansion of clinical trial in Malaysia. As part of CRM's commitment to growing the capacity of our researchers in early phase research, CRM have sponsored Dr Voon Pei Jye's fellowship training in early phase oncology at Princess Margaret Cancer Centre. This sponsorship completes CRM's Phase 1 Realization Project (P1RP) which was conceived in 2016 and executed in stages to develop Malaysia's early phase clinical trial capability. We have also formalized our partnership with National Cancer Center Japan, one of the leading oncology centers in the world. This collaboration, which focuses on our developing site infrastructure and capacity building, also provides our researchers the opportunity to participate in international collaborative research projects within the region, especially in early phase cancer genomic projects. And in the latest development, Malaysia has been identified as a site for a most-sought for sponsored COVID-19 vaccine trial, involving eight public hospitals. Being chosen in global vaccine trial is true testament to the experience and skills our research team have built in multinational clinical research.

I would like to take this opportunity to thank everyone in CRM for striving hard despite the pandemic. It may have been a challenging year, but the clinical research industry has adapted to many new ways to ensure continuity in operations that is now the new 'norm'. It is our hope that everyone continues to stay safe and well during these times and adhere to the Standard Operating Procedures by the Ministry of Health.

Dr. Akhmal Yusof
CEO, Clinical Research Malaysia

www.clinicalresearch.my

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HIGHLIGHTS

CRM Virtual Industry Dialogue 2020

KUALA LUMPUR, 17 & 21 July 2020 – CRM conducted its very first virtual Industry Dialogue in 2020. It was carried out for 2 days, consisting of webinar and live dialogue session. Over 130 delegates (representing sponsors and CROs) participated in sessions which had updates and in-depth dialogue by MREC, NPRA and MDA on the new norms of clinical trial.

13th National Conference for Clinical Research (NCCR)

SETIA ALAM, 24 - 26 August 2020 – CRM co-organized the 13th NCCR together with ICR. The conference was officiated by the Minister of Health, Dato Sri Adham Baba in NIH. All sessions in the 3- day conference was conducted virtually. One of the highlights of the conference was the symposium by Prof Kiat Ruxrungtham (Head researcher at Chulalongkorn University's Centre of Excellence in Vaccine Research and Development) who shared on the global progress in Covid-19 vaccine development.

BFM 89.9 "The Bigger Picture"

KUALA LUMPUR, 9 September 2020 – CEO of CRM, Dr Akhmal Yusof joined BFM's 'The Bigger Picture' program, in a live discussion on clinical research and its progress in Malaysia.

Astro Awani "Consider This"

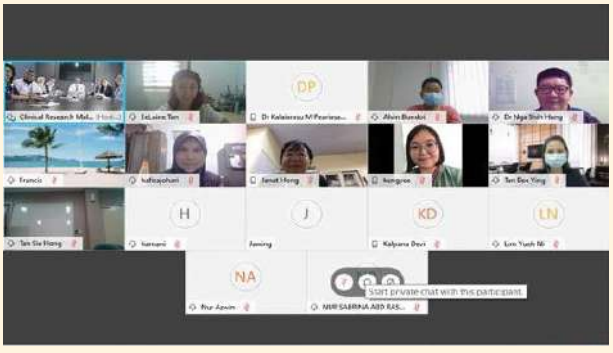
KUALA LUMPUR, 24 September 2020 – Dr Akhmal spoke on clinical research development, benefits and its regulation at Malaysia in Astro Awani's "Consider This" program with Melisa Idris and Sharaad Kuttan

Sin Chew Daily (Healthcare) Newsletter

KUALA LUMPUR, September 2020 – CRM's CEO was featured in Sin Chew Daily (Healthcare) Newsletter, where Dr Akhmal Yusof shared his insights on clinical trials practices in Malaysia, covering informed consent, ethics, regulation, and patients' rights in trials. In another issue, also by Sin Chew Daily (Healthcare), Dr Akhmal shared on Public Readiness and Emergency Preparedness Act (PREPA) and its relevance in Malaysia.

CRM's 2nd Board of Directors Meeting

KUALA LUMPUR, 25 September 2020 – CRM held its second Board of Director Meeting, chaired by YB Dato' Sri Sr Adham Bin Baba, Minister of Health Malaysia. Meeting was held in CRM HQ Office.



CRM Virtual Investigator Dialogue 2020

KUALA LUMPUR, 9 & 12 October 2020 – Following the success of the virtual Industry dialogue, CRM conducted its very first virtual Investigator Dialogue. It was carried out for 2 days, consisting of webinar and live dialogue session. Close to 50 participants from various study sites as well as representatives from ICR & MREC joined the dialogue which saw discussions on current remote trial practices and the shift towards a more virtual trial conduct.

CRM's 3rd Board of Directors (BoD) Meeting

KUALA LUMPUR, 18 November 2020 – CRM held its 3rd BoD via virtual platform with full quorum presence. The management presented the YTD achievement which showed good results & subsequently received approval to the proposed strategies & budget 2021.

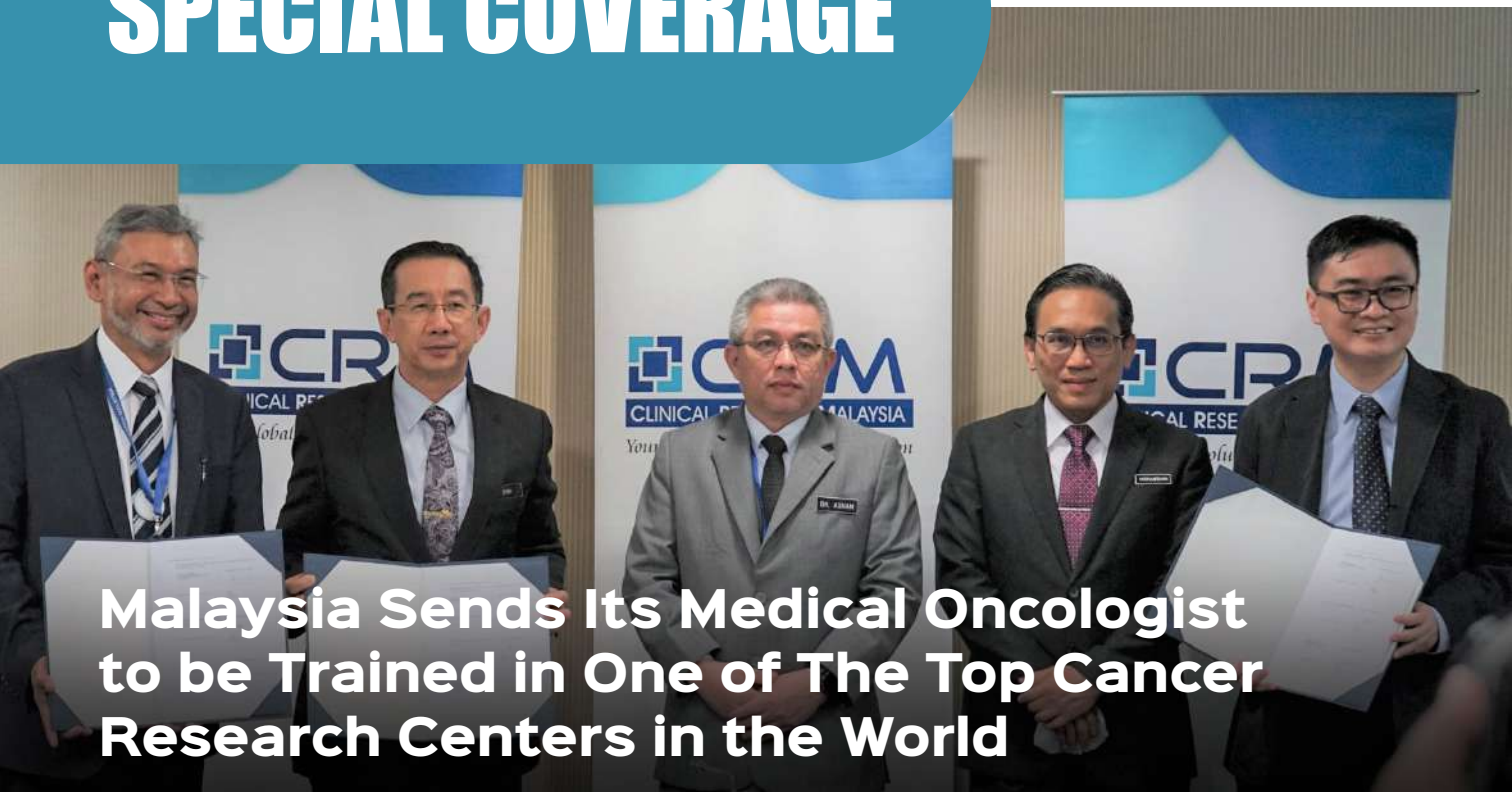
ISO 9001:2015 2nd Surveillance Audit

KUALA LUMPUR, November 2020 – Clinical Research Malaysia have successfully completed its 2nd year of SIRIM Surveillance Audit for ISO 9001:2015 Quality Management System and have received recommendation for continual of certification.

First COVID-19 Vaccine Trial in Malaysia

KUALA LUMPUR, 27 November 2020 – Malaysia's first COVID-19 vaccine trial is to begin in December. The Phase III trial, sponsored by Institute of Medical Biology Chinese Academy of Medical Sciences, will be conducted in 8 Ministry of Health hospitals and involving 3,000 healthy volunteers.

SPECIAL COVERAGE



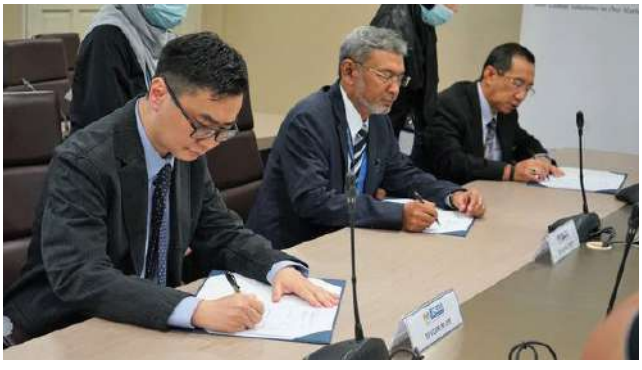
Malaysia Sends Its Medical Oncologist to be Trained in One of The Top Cancer Research Centers in the World

KUALA LUMPUR, 28 July 2020 – The Ministry of Health (MOH) through Clinical Research Malaysia (CRM) sponsored Dr. Voon Pei Jye, Medical Oncologist at Sarawak General Hospital, for a Clinical Fellowship Training at Princess Margaret Cancer Centre which is affiliated with the University of Toronto, Canada. Princess Margaret Cancer Centre is one of the top 5 and largest cancer research centers in the world and focuses on all three areas of research: basic, translational, and clinical research.

For this batch of fellowship, Dr. Voon joins five other oncologists from UK, Spain, and Italy at this internationally renowned cancer center. He is posted at the Department of Medicine, Division of Medical Oncology in Phase 1 for a period of 13 months starting from 1st September 2020. During his time there, Dr. Voon will be participating in multiple research projects and taking up clinical and teaching duties specific to the Phase 1 program including attendance to clinics and ward rounds.

This sponsorship completes CRM's Phase 1 Realization Project (P1RP) which was conceived in 2016 and executed in stages to develop Malaysia's early phase clinical trial capability. This includes development of the Phase 1 Clinical Trial Guideline, capability development (ie. Phase 1 scientific panel setup), people development (ie. postgraduate trainings for regulatory officers) and preparation of a Phase 1 trial site (Sarawak General Hospital accredited as a Phase 1 Unit by the National Pharmaceutical Regulatory Authority late last year). With Dr. Voon's acceptance into the University of Toronto Phase 1 Program, Malaysia would be ready for early phase clinical research particularly in First-in-Human trials.

Signing on behalf of the MOH is the Secretary General of the Ministry of Health, YBhg. Dato' Seri Dr. Chen Chaw Min and the Chief Executive Officer of CRM, Dr. Akhmal Yusof. The ceremony is witnessed by Health Minister, YB Dato' Sri Dr. Adham Baba. *"The attachment of Dr Voon will move the country a notch further in moving away from late phase to early phase clinical trials, enabling local drug development and providing treatment options for patients who are not responding well to the current standard of care"* said Dr Adham.



Malaysia Partners with Japan's Top Oncology Hospital to Focus on Oncology Drug Development

KUALA LUMPUR & TOKYO, JAPAN, 30 October 2020 – Clinical Research Malaysia inked a Memorandum of Understanding (MoU) with the National Cancer Center Hospital to develop Malaysia's capabilities and capacities in oncology clinical research. As one of the partners in Asia for the ATLAS (Asian clinical TriaLs network for cAncerS) project established by the National Cancer Center Japan (NCCJ), Malaysia will benefit from early phase oncology drug development, cancer genomic medicine advancement and drug access and development.

The National Cancer Center Hospital (NCCH) that will be leading this project, is the region's leading cancer hospital located in Tokyo and was recently rated Top 20 among 'World's Best Specialized Hospitals 2021 in Oncology' by Newsweek. It was designated an AMED (Japan Agency for Medical Research and Development) Global Clinical Trial Core Center in 2016 and has since scaled up its international clinical trials activities.

The MoU with NCCH spells out collaboration in the areas of cancer research that includes infrastructure development, training opportunities in clinical research, participation in rare cancer clinical trial, networking opportunities as well as visits/attachments by research experts from both countries. This will further pave the way for better Malaysia-Japan collaborations in advancing drug development.

"Upon launching the ATLAS project for establishing a clinical research network with our Asian partners, CRM stood out as the experienced and reliable partner to the project, as well as being the most forthcoming in collaborating with us. Through implementing this ambitious project, we wish to establish a sustainable clinical trial network, share capacity building

opportunities, and facilitate early drug development. Through clinical trials in Asia, we can bring about better cancer treatments, eventually delivering to cancer patients in Asia," said Dr. Kazuaki Shimada, Director of the NCCH.

The MoU signing ceremony took place on a live virtual platform and was signed by both Dr. Shimada and the CEO of CRM, Dr. Akhmal Yusof. The signing of the MoU was witnessed by the Deputy Director General of Health (Research & Technical Support), Dr Hishamshah Mohd Ibrahim, on behalf of the Health Minister of Malaysia and Dr Teiji Takei, Assistant Minister for Global Health and Welfare from the Ministry of Health, Labour and Welfare, Japan.

"As a result of our experts' visit exchanges these past two years, we are fortunate that CRM is committing to render full support for quality clinical trials. Today, by concluding a memorandum of understanding on cooperation with Clinical Research Malaysia, we mark a milestone in establishing our relationship," Dr Hitoshi Nakagama, President of National Cancer Center Japan quoted.

"Malaysia welcomes the Japanese Government and National Cancer Center Hospital initiatives to reinforce clinical trials infrastructure in Malaysia through the launching of the ATLAS project. The Ministry of Health through CRM will ensure the success of this project through delivery of quality clinical trials in Malaysia. We also acknowledge the immense effort that was put in place to materialize the Japanese Government's vision in promoting Universal Health Coverage in this region," said Dr Hishamshah.

RESEARCH PERSONALITY

Professor Dr How Soon Hin

Professor of Internal Medicine, Kulliyyah of Medicine, International Islamic University

Consultant general physician and chest physician, Hospital Tengku Ampuan Afzan

About Professor Dr How Soon Hin

Professor Dr How Soon Hin graduated from University Malaya, Kuala Lumpur in 1996 and obtained Master in Internal Medicine in 2002 from the same university. He is currently a Professor of Medicine, Kulliyyah of Medicine in International Islamic University Malaysia (IIUM). He is also a consultant general physician and chest physician in IIUM Medical Centre, Hospital Tengku Ampuan Afzan and Darul Makmur Medical Centre.

Prof How's research interests are mainly on melioidosis and lung cancer. He is also involved in several multi-center randomized control study on asthma and chronic obstructive pulmonary disease. To date, Prof How has carried out over 30 sponsored clinical trials and published over 60 articles in both local and international journals.

Can you tell us what first sparked your interest to get involved in clinical research?

My introduction to research began over a decade ago, after being encouraged by Dr Lim Teck Onn, then Director of ICR. The first study I was involved in then was a pneumonia study, in which I was a co-investigator. Subsequently, I became principal investigators for a few clinical trials on asthma, COPD, lung cancer, pneumonia, thrombosis, pulmonary embolism etc.

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

One of the advantages of clinical trials is to be able to access new innovative treatment which is costly to our patients. Most of my studies are in lung cancer now because many of my lung cancer patients cannot afford newer therapy ie. Immunotherapy and targeted therapy. By participating in clinical trials, my patients could access to these newer therapies which improve their quality of life and prolong their survival.

What are the main challenges you encounter when conducting a clinical trial and how do you overcome them?

Time. Time is often a challenge when conducting clinical trials especially I am a clinician, a lecturer and conducting my own research as well. At times, I need to manage my time by working after office hours and even on weekends to fulfil my role as a clinician, lecturer, researcher, and a clinical trial investigator.

In your opinion, how would you encourage young/new clinicians to participate in clinical trials?

Being in a senior position, I feel guidance is very important. I often guide my co-investigators to become principal investigators and encourage them in taking up more trials. I always remind them on how clinical trials could help our patients and benefit the study team through the knowledge, experience and remuneration received.

What is your motivation behind conducting clinical trials?

Watching my trial patients recover and getting better drives my motivation to conduct more trials. Even my study team members, including my study coordinators, are happy when they see trial patients recover and having positive results from participating in the trial. A lot of our stage 4 lung cancer patients treated with immunotherapy in the clinical trial setting survived for more than 5 years, which I have not seen in the era of chemotherapy. And most of them have good quality of life without further therapy.

Over the years, more and more lung cancer trials come to Malaysia, and we have more young investigators who are enthusiastic in lung cancer trials. This will benefit more patients in Malaysia. We also gain more experiences on the usage of the new therapy through conducting clinical trials.

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

Busy. I could only think of busy. But much of my workload have reduced with the support of my colleague, Dr Aishah bt Ibrahim and Dr Megat Rezeem who have been helping me a lot. It has lightened a lot of my workload and now I could focus into conducting my own investigator-initiated studies (IIR). It is through the experience & knowledge that I have gained in the years conducting clinical trials that have enabled me to initiate my own studies. Special thanks to my study coordinators (Adibah, Samiah, Ezati etc) especially from CRM who help me a lot, day and night, even over the weekends.

In your opinion, how has clinical research evolved over the past decade? In the field of clinical research, where do you wish to see Malaysia in the next 10 years?

I feel clinical research in Malaysia has really grown and that CRM has done a good job in bringing in clinical trials. I remember, over 10 years ago, not many sponsors/ CROs would choose Malaysia as a research destination due to limited active trial sites. Now I can see more active trials sites in public hospitals.

I believe the clinical research industry in Malaysia will grow substantially. I have continuously encouraged more clinicians and train more doctors to conduct clinical trials. I hope that when they return to their respective institution, they would be able to carry out clinical trials on their own. Among researchers interested in lung cancer, we have set up a Lung Cancer Research Network, to collect more data on lung cancer, to exchange knowledge and to initiate investigator initialled research.

What do you think are the barriers that prevents most doctors from participating in clinical research?

I would say is most occasions, its time. Experience could also be a factor, but I think the main challenge would be time, especially for clinicians with young families. On most occasions, one would need to work after office hours and weekends for paperwork, like answering trial queries, reviewing SUSAR, answering e-mail, etc.

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?

I suppose this has been raised for many years. We have many doctors, especially in public hospitals, and one major change could be in Ministry of Health providing a dedicated day for our clinicians to conduct clinical trials, be it investigator-initiated study or sponsored trial. This is a common practice in many institutions overseas, to give protected time for investigators to carry out their trials. This will provide ample of time for clinicians to take up clinical trials and even conduct and publish their own studies.

I believe clinical trials are very useful to our patients, especially those with cancer and autoimmune disease conditions requiring expensive treatment. So, I believe that CRM can play a huge role in creating awareness of clinical trials to the public and making it more accessible to our patients.

As we aim to encourage more young investigators to venture into clinical trials, if you do have any additional journey insights, experiences, or any messages at all?

I believe by giving protected time for clinicians to conduct research would further encourage many more to take part in clinical trials. It is also important for principal investigators to train their co-investigators to become principal investigator in the subsequent study, for them to kickstart their journey as principal investigators.

Standing (L-R): Noor Sami'ah Mukhtar, Sister Yau Mee Tin, Adibah Hamizah
Seated (L-R): Dr Aishah Ibrahim, Prof How Soon Hin, Dr Megat Razeem

RISING STARS IN PAEDIATRICS

Dr Amelia Binti Alias
Paediatrician and Paediatric Cardiologist

Hospital Raja Perempuan Zainab II, Kelantan

My interest is mainly on cardiovascular disease. I am particularly interested in area of pulmonary hypertension, congenital heart disease treatment and intervention and fetal echocardiography. My mentor, Professor Abdul Rahim Wong, advised me to join my first clinical research. He believes that research can help open new doors that may benefit patients' future treatment and management. An advice that I am glad to follow.

My patients and the support of a good research team drives me to be involved in clinical trials. In the study I'm currently involved in, I am able to offer new alternative medication to my patients. Another important factor is having a good research team. I am very lucky to have a supportive and dedicated clinical research team in Hospital Raja Perempuan Zainab II. I was a complete novice in research when I joined. My team, particularly Mr Ahmad Naqiuddin, have been very patient and supportive towards my development in clinical research. A good team absolutely make challenging clinical research appear easier and interesting & I would definitely recommend my peers to take up clinical research. Clinical research can be intimidating for beginners but the outcome that benefits patients will certainly give you a new job satisfaction. Clinical research also allows you to keep up to date with new treatments in your field of interest.

Dr Chieng Chae Hee
Consultant Paediatrician & Head of Neonatal Unit

Hospital Sibu, Sarawak

When CRC Sibu was established in 2011, we were approached for feasibility studies by sponsors with help of CRM. That was the starting point for me to get involved in global clinical trials. I had the opportunity to be investigator for nine clinical trials including principal investigator in three studies. Conducting clinical trials has made me a better clinician. Knowing how tedious the consenting process in clinical trial is, I have learned to be more thorough in taking consent from patients for clinical procedure. I think it is very important to keep our patients well informed of the treatment process to avoid any miscommunication. Also, I learned to practice good documentation in day-to-day practice as I have learned from clinical trial the importance of doing so. I have gained extra knowledge on how to conduct own research and also started to realize the importance of sound methodology in any research to improve its validity.

The main motivation for me to be involved in clinical trials is to improve our patients' care now and in future. We know that conducting clinical trial is the only way to get new, hopefully better treatment option for diseases and to promote new advances in medical care. Some of my study subjects responded very well to the new treatment and continue to receive them after completion of the study. Besides, our patients' care can be better as we can utilize the funding generated via conducting global clinical trials. In my department alone, we have managed utilized the funding to equip the department with ventilator, AABR machine, vital signs monitor & installing medical gas system. I hope to continue being involved in clinical trials and encouraging my junior doctors to join as well as we make Malaysia a popular site for global clinical trials.

Dr Hannah Tan Pei Koon
Paediatrician
Hospital Miri, Sarawak

I was first exposed to clinical research in 2017 when I was given the opportunity to be a sub-investigator for a hematological related trial. As a novice, I found the complexity of conducting trials in children to be intimidating and time consuming. However, the exposure gave me many new experiences and reinforced my beliefs that clinical research is fundamental for improving care for all children. Conducting trials has made me be more thorough and careful in my documentations. I could fully comprehend the importance of being transparent, meticulous, and conscientious in my daily clinical practice. It has also taught me to be more flexible and diligent in time management as I still need to carry out daily clinical duties on top of conducting research. I could never have succeeded without the assistance of my wonderful team at Miri General Hospital.

Clinical trials represent the promise of future progress of groundbreaking treatments. It is an evidence-based confirmation or improvement of existing practices and policies. For some patients, it is a hope in dark times when all current available treatments have failed, while for others, it is the altruistic desire to help future generations. I believe clinical research is an investment into better evidence-based treatment for all the children which directly translate to better healthcare for all. More often than not, while doing literature search, one will encounter the phrase 'however, there is inadequate data to recommend the use in children'. Child health research is gaining momentum and is now a priority in the international agenda. Although undertaking research in children is more challenging given the complex involvement of parents and family members and the greater risk of liability, the rewards are also twice as much.

> **Being able to offer new alternative medication to my patients drives me to be more involved in clinical trials**
>
> *Dr Amelia*

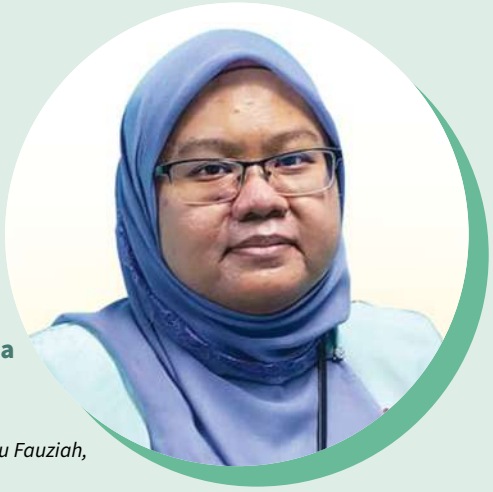
> **I believe clinical research is an investment into better evidence-based treatment for all the children which directly translate to better healthcare for all**
>
> *Dr Hannah Tan*

Dr Kong Wei Nin
Paediatrician

Hospital Sibu, Sarawak

My first encounter with research was when I was a fourth-year medical student in university. It was an indelible learning experience to me, as our group not only won a prize, the months we spent working together as a team has also strengthened our friendships and created lots of fond memories. Over the years, I am blessed to have worked with people with huge passion towards research and value research as a substantial part of a doctor's life – from the hospital director to the consultants to my fellow peers. My consultants have always ensured that the junior doctors are given every opportunity to participate in research and clinical trials. Hence, clinical trials have been part and parcel of my career and training ever since I was still a medical officer – a rare privilege indeed. I am particularly grateful to Dr Toh Teck Hock, my consultant who also heads the CRC in my hospital, pushed me to take up roles in clinical trials which were once seemingly impossible to me. He has given me his full support and guidance with his vast experience, especially when I became the country principal investigator of a multi-center clinical trial last year, all while juggling with hectic clinical work as a junior paediatrician.

As a researcher, I need to keep myself up to date with medical advancement in order to make the best clinical decisions for my patients. Through clinical trials, I learned that patient safety is always our topmost priority, and this applies to every treatment we give to patients. Effective communication skill, which is emphasized repeatedly in clinical trials, is also a key to successful doctor-patient relationship. I aspire to greater heights in paediatrics clinical research. I hope to encourage more junior doctors to take part in clinical research and make it an essential part of our clinical work, as "the common facts of today are the products of yesterday's research".



Dr Siti Akma Binti Ishak
Paediatrician

Hospital Tuanku Fauziah, Perlis

My first exposure on clinical trials was during my Master's program training in PPUKM, under the encouragement and guidance of Prof Syed Zulkifli. My experience and interest developed more especially when I was given opportunity by my Head of Department, Dr. Abdul Nasir Mohamed Abdul Kadher to be involved as site principal investigator for few studies in Hospital Tuanku Fauziah.

By conducting clinical trials, I realized that I am becoming more meticulous and organized upon treating and managing my patient. Every detail of information and events is being documented and analyzed. These makes me thorough in managing my patients. Besides that, I can explore new approach or treatment strategies for better management of patient's illness. Therefore, I really recommend my peers to participate in clinical trials as it is not only beneficial for healthcare personnel, but also for patients. In future, I'm hoping to do more investigator-initiated trial to answer a lot of clinical questions and to be given more opportunities to lead clinical trials and inspire more of my peers to join along.

INFOGRAPHIC

RECRUITMENT ACHIEVEMENTS IN GLOBAL SPONSORED RESEARCH 2020

Malaysia first recruiter | Top recruiter (APAC/GLOBAL) | Global first recruiter

Ankylosing Spondylitis
Hospital Selayang
CAIN457P12301

Bladder Cancer
Hospital Pulau Pinang
MK-3475-992

Chronic Kidney Disease
Hospital Sultan Abdul Halim
TRCA-303(VALOR-CKD)

Heart Failure (Medical Device)
Sarawak Heart Centre
Mid-Q Response Study

Hemophilia A or B
Hospital Ampang
Feiba 91501

IgA Nephropathy
Hospital Tengku Ampuan Afzan
ALN-CC5-005

Neuromuscular Blockade in Paediatric
Sarawak General Hospital
MK-8616-169

Non-Small Cell Lung Cancer
Sarawak General Hospital
CINC280I12201

Paediatric Type II Diabetes Mellitus
Hospital USM
28431754DIA3018 36783

Paediatric Type II Diabetes Mellitus
Hospital Pulau Pinang
28431754DIA3018 36783

Paediatric Type II Diabetes Mellitus
Hospital Sultanah Bahiyah
28431754DIA3018 36783

Pulmonary Arterial Hypertension
Sarawak Heart Centre
A-DUE Study

Venous Thromboembolism
Hospital Raja Perempuan Zainab II
DU176b-C-U312

ROADMAP TO BECOMING AN INVESTIGATOR

SPECIALIST

Are you a specialist in your area of expertise? Often, it's consultants/ specialists who are sought for to conduct clinical trials

GCP

Undergo Good Clinical Practice (GCP) training & pass the GCP examination (Usually organised by CRCs at MOH hospitals & by universitites)

QUALIFICATION

REGISTER

Register your interest to be an inverstigator with the hospital CRC and CRM. Approval and support from your department are especially important in your journey to being an investigator

PARTICIPATE

STUDY TEAM

Join existing/new study teams as a sub-investigator under the supervision of the PI to gain needed experience in conducting clinical trial

PERFORM

Be a valued member in study teams. Perform your role as delegated by PI and always ensure standards of GCP are adhered to

EXPERIENCE

FEASIBILITY

Experienced investigators will be approached by CRM for new feasibility studies. Questionnaires provided would need to be answered accurately within the timeline agreed

EVALUATION

Sponsor/Contract Research Organisation (CRO) will approach site & investigator for further evaluation if post-feasibility assessment is successful

PI

Awarded as Principal Investigator (PI) for site/study if selected. CRM will facilitate PI for study budget and Clinical Trial Agreement review during study start-up

START-UP

REGISTER AS AN INVESTIGATOR

https://clinicalresearch.my/investigator-registration-form/

Clinical Research Malaysia (CRM) facilitates as a one-stop centre for sponsored research. Below are some of the services CRM provides:

- *Feasibility studies & investigator matching*
- *Consultation and management of clinical trial budget*
- *Review of Clinical Trial Agreement (CTA) & Non-Disclosure Agreement (NDA)*
- *Development & placement of study coordinators*

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GLOSSARY

Sponsored Research:
Research that is fully funded by a company/ organisation. Protocol is developed by the sponsor and investigators are 'hired' to conduct the research. Common examples are drug clinical trials by pharmaceutical companies

Feasibility:
A process in evaluating the possibility of conducting the study at a region/site

Contract Research Organisation (CRO):
Research organisation that is outsourced by sponsor to provide research support

Study Coordinators:
Trained and qualified research personnel who support investigator in carrying out delegated study-related tasks

FEATURED SITE

Hospital Wanita dan Kanak- Kanak Sabah

Hospital Wanita dan Kanak- Kanak Sabah (Likas) is situated 7.8km from the heart of Kota Kinabalu, making up a total land area of 25.05 acres. On 11 April 2005, commencement of Phase 1 Hospital Pakar Likas was launched by Dato' Dr. Zainul Bin Hamzah, then Sabah State Health Director. The 658-bed hospital was rebranded to Hospital Wanita dan Kanak-Kanak Sabah (HWKKS) by then Health Minister of Malaysia Dato' Seri Liow Tiong Lai on **9 August 2009**.

Among the main departments in Hospital Wanita dan Kanak- Kanak Sabah (Likas) are the clinical oncology department, obstetrics and gynaecology department and paediatric department. The hospital also has its own one-stop Nuclear Medicine & Radiotherapy Centre, the first one- and the only centre of its kind in East Malaysia. The facility began its operations on **8 April 2013**.

Clinical Specialties in HWKKS:

- Obstetrics & Gynecology (General)
- Reproductive medicine
- Maternal-fetal medicine
- Gynae-oncology
- Anesthesiology
- Haematopathology
- Paediatric (General)
- Paediatric Infectious Disease
- Neonatalogy
- Paediatric Neurology
- Paediatric Endocrinology
- Paediatric Haemato-Oncology
- Paediatric Surgical
- Paediatric Ophthalmology
- Paediatric ENT
- Paediatric Orthopedic
- Paediatric Neurosurgical
- Paediatric Dental
- Nuclear Medicine
- Emergency Medicine &Trauma
- Radiotherapy and Oncology
- Radiology

Total Workforce/ Staff in HWKKS, including contract personnel – 2,218

Doctors
251

Pharmacists
71

Nurses
878

Community Nurses
334

Other supporting staffs
648

Hospital Operations in 2019

Admissions	Discharge	Outpatient including emergency cases	Birth
54,951	53,379	184,247	16,443

CRC Hospital Wanita dan Kanak-Kanak Sabah (HWKKS)

CRC HWKKS was established and started operations in 17 Feb 2011. It was officiated by the Director General of Health, Malaysia, Tan Sri Dato' Seri Dr Noor Hisham Abdullah on 12 September 2018. The centre is currently headed by Dr Flora Chong Li Tze (clinical oncologist) and assisted by Dr Heng Hock Sin (paediatric neurologist) as the deputy.

Official Opening of CRC HWKKS on 12 September 2018

CRC HWKKS Group Photo

Facilities:

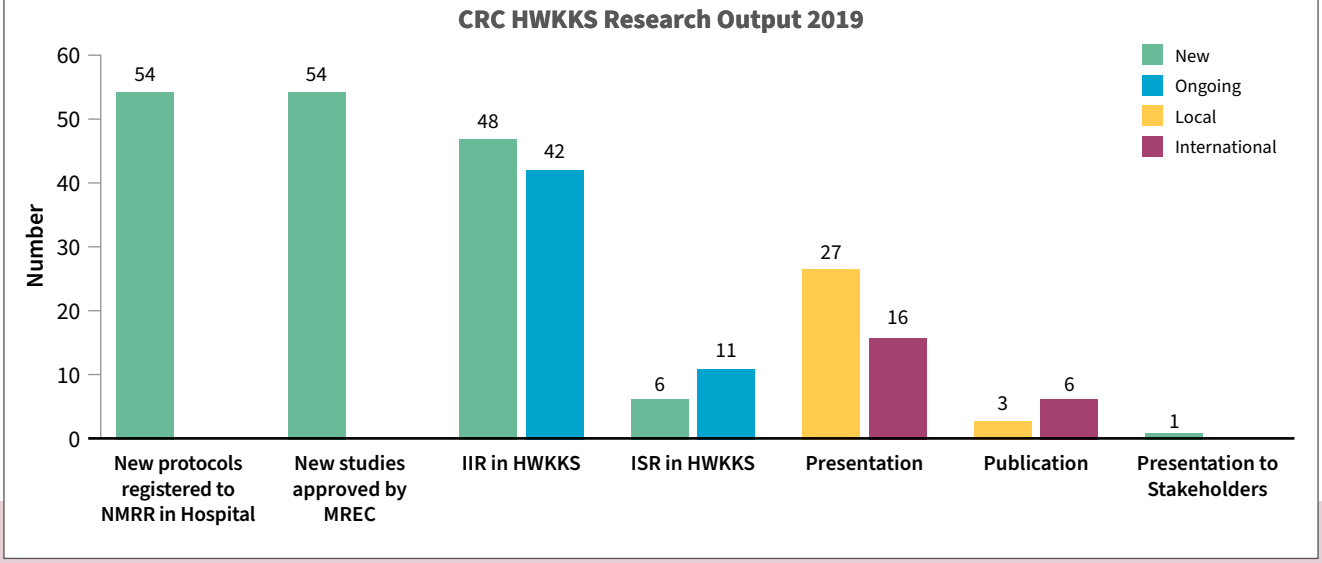
- Freezer (-80°C & -20°C)
- Pharmaceutical Fridge (2-8°C)
- Temperature Monitoring System
- Temperature-Controlled Centrifuge
- Infusion Pump
- ECG Machine
- Vein Finder & BP set
- Documents storage area
- Rooms for meeting/ monitoring/ consultation

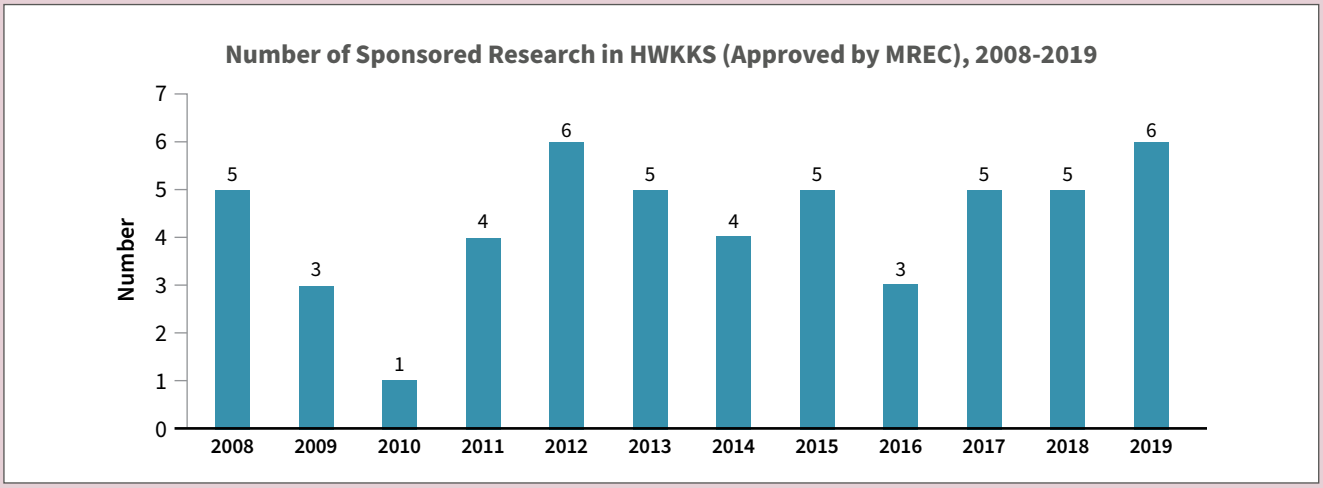

Record Room

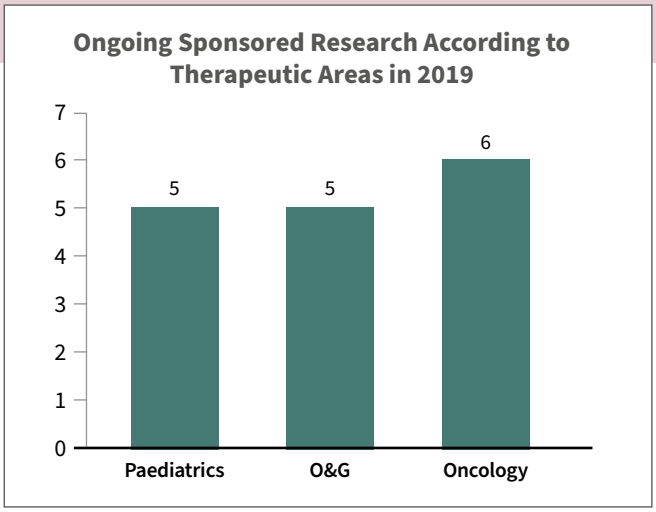

Equipment Room


Consultation Room

Research in Hospital Wanita & Kanak-Kanak Sabah







Site Accomplishments in Sponsored Research

2009 → First Patient-in for Malaysia (Save-Onco Study)

2012 → First Patient-in for Malaysia (Gatsby Study)

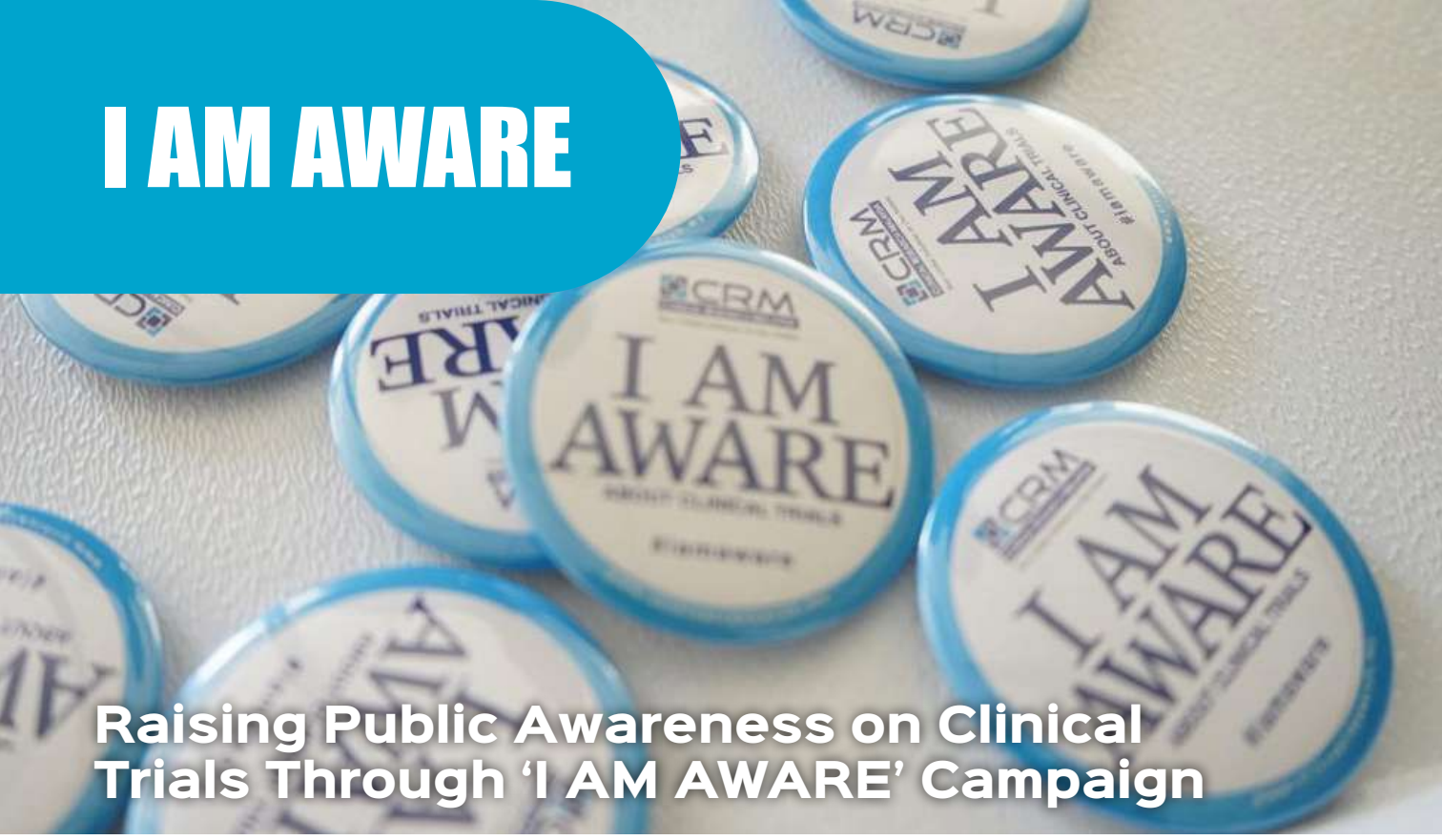
2013 → First Patient-in for Malaysia (Safeher Cohort B Study)
→ First Patient-in for Malaysia (Amgen782 study)
→ First Patient-in for Malaysia (Everexes study)
→ First Patient-in for Malaysia (Metgastric study)

2014 → First Patient-in for Malaysia (Kailee study)

2016 → First Patient-in for Malaysia (Rainbow Study)

2018 → First Patient-in for Malaysia (Asteroid 3 Study)

I AM AWARE



Raising Public Awareness on Clinical Trials Through 'I AM AWARE' Campaign

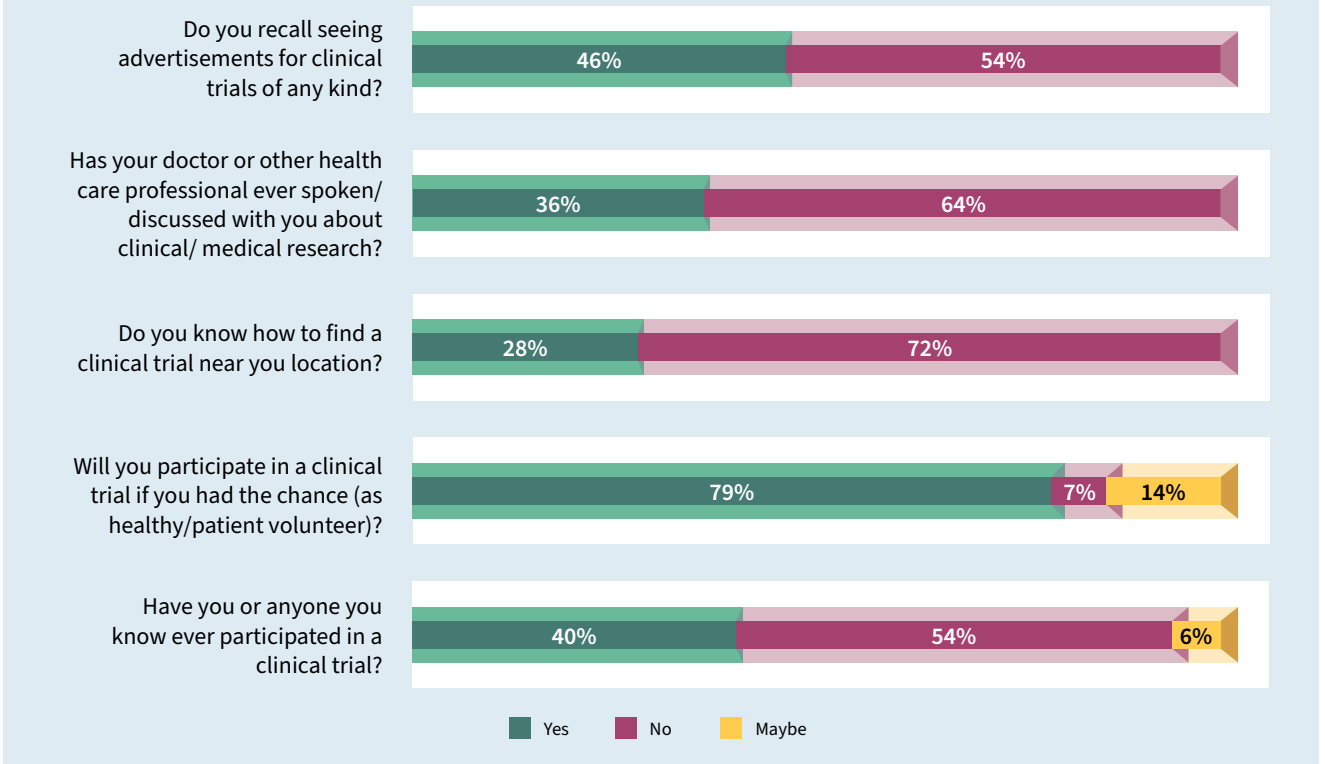
'I AM AWARE' is a campaign by Clinical Research Malaysia, aimed to raise awareness of clinical trials among patients and the public by providing access to information on clinical trials.

In previous years, CRM conducts a series of 'I AM AWARE' roadshows in public hospitals, healthcare clinics and universities across the nation to drive awareness of clinical trials to the community. It is hoped that through this campaign, misconceptions on clinical trials can be addressed, and people may gain better understanding on the risks and benefits of participating in a clinical trial, hence being able to better make informed decisions.

In year 2020, ensuing the COVID-19 pandemic, CRM has taken a fully virtual approach in the 'I AM AWARE' campaign, via CRM's own social media platforms to ensure patients and public are aware & informed regarding clinical trials in Malaysia.

The virtual 'I AM AWARE' provides informative snippets about clinical trials, that are published online in both English and Bahasa Melayu languages. These pieces include information pertaining to trial participants' rights, risks & benefits involved in participating in clinical trials, informed consent process and even on cracking general 'myths' on clinical trials. Social media polls are also carried out engage with the public and to further understand the current perception/ exposure they have in regards of clinical trials.

I AM AWARE
SOCIAL MEDIA POLLS



UP CLOSE

Celebrating Dato' Dr Goh Pik Pin's Journey with Clinical Research Malaysia

In August 2020, Dato' Dr Goh Pik Pin retired from public service, including her position as the Director of Institute for Clinical Research (ICR). She has been an influential figure in the setting up of Clinical Research Malaysia when clinical research was identified as one of the Entry Point Projects under the Healthcare sector of the National Economic Plan in 2010. Since 2012, CRM had a supportive, collaborative and enjoyable working camaraderie with the team in ICR and with the Clinical Research Centres (CRC) at our public hospitals, thanking to the direction she has led the team with over these years. Recently, we have sat down for a brief interview session with Dato' Dr Goh to learn more on the journey she has had with ICR and clinical research.

How did you first get involved in the clinical research industry?

I was first introduced to research during my postgraduate studies and training. Later, during my stint as an ophthalmologist, I was involved in a national eye survey program which brought my interest to public health research, more specifically in prevention of blindness. At that point of time, we realized the importance of maintaining a national eye database/ registry which got me working with the then CRC Director, Dr Lim Teck Onn. After the completion of my fellowship, Dr Lim Teck Onn kindly offered me a desk in CRC which allowed me to carry out both my clinical duties and research activities at Hospital Kuala Lumpur & subsequently Hospital Selayang. When Selayang established a CRC, I was appointed as the Head of CRC Selayang and later on the Director of National CRC when Dr Lim Teck Onn retired from public service. Coincidently, during that time, discussions were ongoing on industry sponsored research being one of the key economic area in the National Economic Plan. Much support was received on this plan which saw the establishment of CRM establishment and the initiation of more hospital CRCs. I was blessed that in many ways, the right things happened at the right time.

Could you share any significant achievements & memories which have made a mark in your journey leading this institute?

It was significant to me to see how evidence gathered from good research could contribute to improving our existing healthcare programs and translated into policy changes for the betterment of our society. For instance, by adapting a WHO protocol, my research team were able to establish refractive errors among the children in Gombak community, and the results of this helped improve the health screening programs that are run in schools. Also, together with the public health researchers in National Health Morbidity Survey program, we looked into retinopathy

among our diabetic population, and this helped improved the policies that were put in place in our clinical practices. Another is on our partnership DnDi, for which we are now able to access effective Hepatitis C treatment, all thanks to trials we have preceded with in confirming the treatment regime. With this in hand, our nation is now on track to eradicate Hepatitis C infection.

I am also very proud of the team in ICR and in our CRCs. It always brings me joy to receive acknowledgment and praises from our partners we work with on the team we have. In CRC, we always place our trust in our people and help nurture their confidence and potential in research. All have the room to grow as a researcher individually, irrespective of their professions as clinicians, pharmacists, or nurses. Even during the pandemic situation, many have been actively conducting studies, analyzing on the data to produce impactful findings that help better manage and care our Covid-19 patients.

What was your biggest challenge as a Director of ICR?

The biggest challenge I felt was in creating the needed scientific exposure for our researchers. There are many potential talents out there, however, our institutions are unable provide a more conducive scientific environment to grow our research capabilities, unlike other similar institutions abroad that are often affiliated to reputable research universities. We do however send some of our researchers abroad for attachments/ trainings or even bring in experts to share their knowledge with our team, but there are always limitations to this approach. Hence, more needs to be done in creating a more beneficial environment for research within our Ministry of Health, to recognize their capability and provided the needed tools for them to flourish. Hopefully in future, our public service system would adapt to seamless transitions within the organization, which would allow our MOH officers for room to do more groundbreaking innovative research.

Any advice for our healthcare professionals and future researchers in this field?

It is important to find joy and delight in whatever you pursue. With joy, you can overcome any challenges you face along the way and there is much enjoyment in the process of achieving the outcome. Also, to those who are doing or wish to pursue research, it is important to always have perseverance and not limit oneself to aspirations of fame, praise and material gains, but rather of doing good for the benefit of others.

> **Thank you very much for all you have and are doing in promoting and enabling clinical research to be conducted in Malaysia, especially in MOH. CRM has done well and I am confident it will flourish. MOH's potential in doing better and impactful research need continuous support from CRM. Wishing you all the best**
>
> *Dato' Dr Goh Pik Pin*

PUBLICATIONS

Establishing Clear Procedures and Improving Start-up Timeline in Malaysia's Clinical Research Ecosystem

Article published in Journal for Clinical Studies, Volume 12 Issue 2, 17 April 2020

By Audrey Ooi and Noorzaihan Mat Radi, Clinical Research Malaysia

Abstract

As delays in getting clinical trials up and running have financial implications, pharmaceutical companies and contract research organizations (CROs) are looking at ways to accelerate the study start-up process. Challenges in processes such as feasibility assessment, site selection, compilation of essential documents, submission to ethics committee, and application for investigational product release can affect study milestones and timelines.[1,2]

In Malaysia, the Clinical Research Malaysia (CRM)'s role as the one-stop-centre to advance industry sponsored research in the country, include ensuring efficient start-up processes. The organisation offers services such as feasibility assessment, budget negotiation, clinical trials agreement review and placement of study coordinators. This article describes CRM's timeline in feasibility assessment, budget negotiation and clinical trial agreement review, besides the regulatory and ethics approval timeline in Malaysia.

Centralised Feasibility and Site Selection Services

The company has a centralised feasibility team that handles feasibility queries from CROs, pharmaceutical, medical device, and biotechnology companies. The feasibility team maps the sites according to disease specialities and workload, saving the time it takes to identify the right investigators and sites with interest in a particular clinical trial. It also assists interested potential investigators to address the queries and submits the completed feasibility questionnaire to the CRO or sponsor (Figure 1). Having a centralised service is far more efficient as the individual databases of the CROs and sponsors may not always be updated and sufficiently comprehensive.[3]

As the single point of contact, the standardised processes lead to streamlined communications which reduce delay and confusion on the ground. As a result, the turnaround time is shorter than if a sponsor or CRO were to approach individually. With CRM's central database and feedback from the sites and investigators, a completed feasibility questionnaire can be sent back to the enquiring company within 5–10 working days (Table 1).

Prompt Review and Negotiations of Clinical Trial Contracts

The top cause of delays in clinical trial start-up time is related to contract and budget negotiations.[1,4] Lack of effective communication, unclear processes, bureaucracy, and difficult to understand contracts can lengthen the time it takes to finalise the clinical trial agreements (CTAs).[4,5] To address these challenges, an experienced legal and regulatory affairs department reviews and endorses CTAs (on behalf of principal investigators) for all clinical trials conducted at public hospitals in Malaysia within 14 calendar days, from the last feedback received from the party involved in the study budget negotiation (Table 1). In addition to an experienced legal team, CRM has implemented an online system for submission and internal review of CTAs to shorten the timeline for review. Prior to this, the average time to review a CTA was 59 days.

Parallel Ethics and Regulatory Approval Processes

Clinical trials that are conducted in the Ministry of Health (MOH) facilities will require ethics approval from the MREC (Medical Research and Ethics Committee), which is the sole ethics committee for Malaysia's MOH facilities. MREC also acts as an independent ethics committee for facilities outside the MOH who do not have their own ethics committees.

Malaysia's regulatory authority for pharmaceutical trials is the National Pharmaceutical Regulatory Agency (NPRA). The NPRA is responsible for approving applications for clinical trial import licence (CTIL) and clinical trial exemption (CTX). Ethical approval is needed before the CTIL or CTX is released (Figure 1).

Study start-up processes	Timelines
Feasibility assessment	5–10 business days
Ethics approval*	50 business days
Regulatory approval* • Clinical Trial Import License (CTIL)/ Clinical Trial Exemption (CRX) approval • Notification of Exemption from Registration of Medical Devices for Clinical Use and Research Supportive Use	 30 business days 14 business days
Clinical Trial Agreement review	14 business days

*Parallel submission

Table 1. Clinical study start-up timelines in Malaysia

For medical device trials, the Medical Device Authority (MDA) oversees the issuance of the letter of no restrictions for notification of medical devices for clinical use and research supportive use. This would take 14 working days. On the other hand, notification of medical devices for clinical investigational use will go through a review by the Technical Committee of Medical Device Clinical Evaluation (TCMDCE). The issuance of a letter of no restrictions would take seven working days after evaluation by the committee. In 2019, an online system was introduced to facilitate the process.

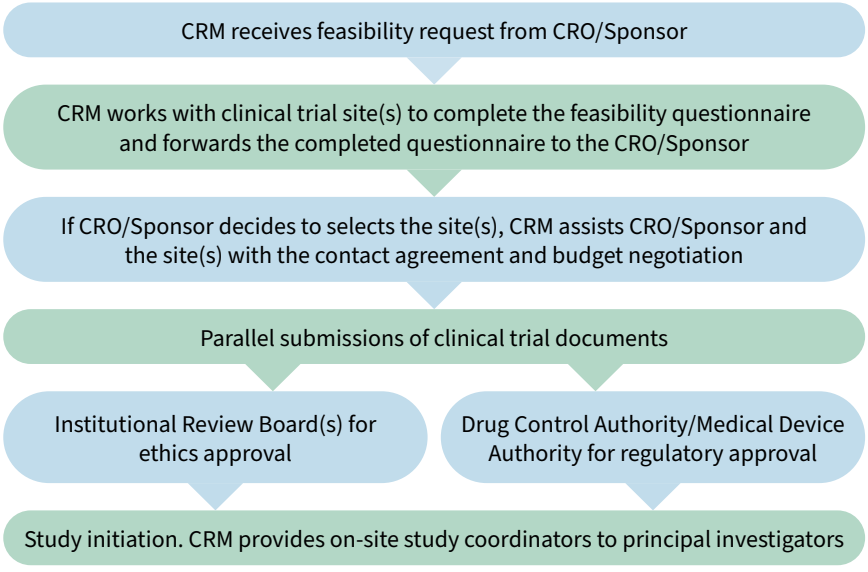


Figure 1. Clinical trial start-up in public hospitals in Malaysia: from feasibility to study initiation

Applications and tracking of progress are done through a local online registration of clinical studies, the National Medical Research Register (NMRR). With the NMRR being linked to the MREC, ethics approval processes are fast and convenient. An NMRR registration is also needed for CTIL/CTX application.

In Malaysia, regulatory and ethical submissions are done in parallel.[6] Regulatory approval takes approximately 30 business days while MREC ethics approval takes about 50 business days[7,8] (Table 1). Ethical review and approval can be as short as one month from the time of application if there are no issues/queries.[8,9] On average, it takes about four months to obtain regulatory and ethics approval.[10]

Conclusion

Consistent timelines, reliability and efficient processes are important criteria for sponsors and CROs in deciding where to conduct its clinical trials. With CRM's involvement at the feasibility and startup phase, as well as a standardised process for regulatory and ethics approval, sponsors will have better understanding and assurance on the timeline, processes and reliability of conducting clinical trials in Malaysia.

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To Participate or Not Participate: Why Do Investigators Reject A Clinical Research?

Article published in Journal for Clinical Studies, Volume 12 Issue 4, 8 September 2020

By Tan Bee Ying, Audrey Ooi & Noor Zaihan Mat Radi , Clinical Research Malaysia

Abstract

Clinical research is a complex, expensive, time- and resource-intensive process. Feasibility assessments play a crucial part in this clinical research planning process as it enables the sponsors and contract research organisations (CROs) to evaluate the possibility of conducting clinical research in a particular region or country with the objective of optimising the project completion in terms of timelines, patient enrolment and cost. Investigators are the key individuals in conducting clinical research and their level of engagement has a significant impact on the success or failure of the study. Understanding the reasons of feasibility rejection among the investigators may provide insights into the internal and external factors that affect the uptake of clinical trials, while at the same time being particularly important when developing policies and interventions to promote clinical research in the country.

Background

Clinical research is the backbone of evidence-based medicine and trial outcomes are crucial for comparing and improving the use of drugs, vaccines, medical devices, and diagnostics. The process of conducting clinical research is complex, expensive, time- and resource-intensive. Thus, clinical research feasibility assessment comes into play whereby the sponsor or contract research organisation (CRO) will be evaluating the possibility of conducting clinical research in a particular region or country with the objective of optimising project completion in terms of timelines, patient enrolment and cost.

Clinical Research Malaysia (CRM) is a site management organisation for the Ministry of Health Malaysia. It is a one-stop contact point for sponsors and CROs who plan to conduct clinical research in the country.[1] CRM has established an extensive database of Malaysian investigators in clinical research, as well as trial site facilities/infrastructure in the public and private healthcare sectors. This enables the company to match the clinical research with the right investigators and sites.

There are usually two types of feasibilities provided by CRM:

Pre-feasibility assessment is information collected for preliminary, macro-level assessment to assist sponsors and CROs to decide which country is suitable to place the study. This assessment includes details on the standard of care, the clinical research registration process, epidemiology, and patient pool.[2]

A full feasibility assessment is a complete documentation narrowed down to individual site, which necessitates confidential disclosure agreement, protocol synopsis and site assessment questionnaire.[2]

It includes but is not limited to patient recruitment rate based on the study protocol, site and investigator's facilities, resources, experiences, and ethics approval.

Feasibility assessment can determine the most suitable trial sites and investigators to conduct specific clinical research. This study aims to evaluate the investigator's engagement rate in feasibility response and identify the reasons for refusal to participate in clinical research.

Methodology

Data extraction from the CRM feasibility assessment database was carried out from 1st January 2019 to 31st December 2019. A total of 348 feasibility assessments were conducted, with 212 and 136 being pre-feasibility and full feasibility assessments, respectively.

Results

The top three therapeutic areas from full feasibility assessment conducted by CRM in 2019 were oncology (n=35, 25.55%); followed by gastroenterology (n=18, 13.14%) and haematology (n=16, 11.68%). These full feasibility assessments were sent out to 466 investigators in 72 hospitals throughout Malaysia. CRM's database received 1059 responses from the investigators for the 136 full feasibility assessments. The majority of the investigators, 55.34% (n=586) agreed to participate in the respective clinical research; while 40.04% (n=424) declined to take part and 4.63% (n=49) did not respond.

Figure 1 shows the reasons for refusal to participate in clinical research among Malaysian investigators. The most common reason given by investigators is insufficient or lack of patient pool at the study site (n=120, 28.30%). This is followed by approached investigators referring the feasibility assessment to their colleagues (n=60, 14.15%), insufficient time to conduct clinical research due to routine clinical work (n=49, 11.56%) and investigators conducting competing clinical research (n=49, 11.56%).

Besides, about 9.43% (n=40) of investigators rejected the feasibility assessment due to study protocol which required strict inclusion and exclusion criteria. In addition, 7.78% (n=33) were not interested in the study and 6.37% (n=27) turned down the study because of the lack of resources in conducting the clinical research. Insufficient time due to other trials is also one of the reasons investigators reject the feasibility assessment (n=20, 4.72%). Other reasons, which made up 4.25% (n=18) of the total responses, are disease-/treatment-related (n=8), patient-related (n=7) and investigator-related (n=3). The remaining 1.89% (n=8) of the responses did not specify the reason for refusal.

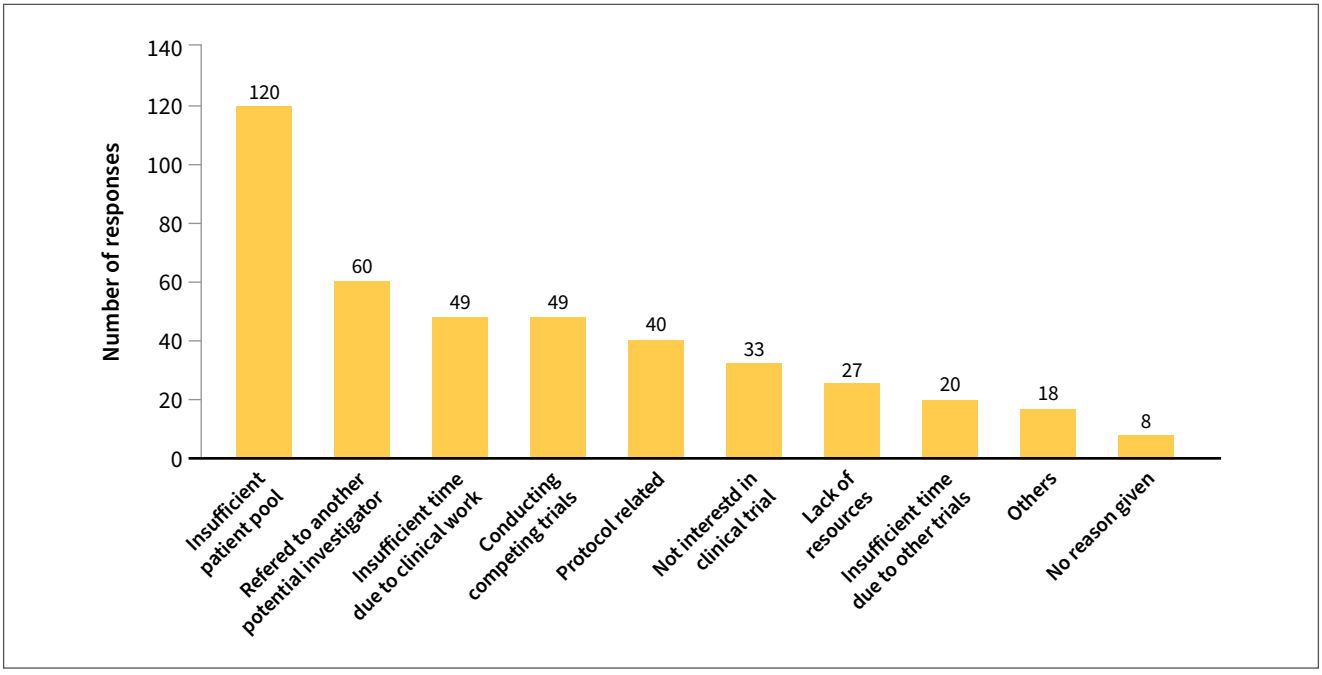

Figure 1: Reasons for feasibility assessment rejection among Malaysian investigators in 2019

Discussion

More than half of the investigators responded positively to feasibility assessment because of the accurate mapping of potential investigators by CRM feasibility specialists, coupled with investigators being well informed on the importance of clinical research, thus reflecting their interest to contribute to the new science of medicines. Investigators will be up to date on the latest treatment and will be able to treat patients based on scientific evidence,[3] thereby improving their clinical acumen.

An insufficient patient pool was the main reason for rejection. Investigators tend to reject low incidence and rare diseases studies, such as autoimmune pulmonary alveolar proteinosis, acromegaly, and low-grade glioma. Furthermore, these diseases are not commonly found among Malaysians and investigators may encounter difficulty in identifying the right patient pool to enrol in clinical research.

Next, investigators also reject feasibility assessment due to the study protocol. This includes complicated protocol, a study involving the multidisciplinary specialist team, close and long duration of follow-up, as well as strict inclusion and exclusion criteria. Oncology studies, for example, have exclusions such as prior chemotherapy, advanced stage of disease or not being newly diagnosed cancer patients. This will lead to a narrow inclusion criterion which may increase the recruitment timeline. As a result, investigators were unable to recruit enough patients for the study within the expected timeline and the sponsor may eventually need to amend the study protocol to recruit additional patients.[4]

A few public hospitals practise hierarchical organisational structure, whereby all the feasibility studies to those sites will have to go through the Head of Department for first-round evaluation before responding to the feasibility assessment either as a team or referring the study to other investigators.

This led to the reason of referral to other potential investigators as one of the common reasons for investigators' rejection. Besides, referral of feasibility assessment to other investigators may also be an effort for experience investigators to nurture and develop new investigators in conducting clinical research.

Insufficient time due to clinical duty and conducting competing trials are among the common reasons investigators reject clinical research. In the public health sector, clinical service remains the investigator's main priority and with the high volume of patients at these hospitals, the challenge of conducting clinical research is real. Clinical research with extensive follow-up as well as those that require long discussions with patients (patient consent, protocol etc) may increase the tendency of investigators to reject the trial.[5] On the other hand, it is common practice in Malaysia that one investigator is dealing with multiple sites or hospitals, thus they may not have protected time to conduct clinical research.

Other reasons for feasibility rejection include patient-, disease-/treatment-, and investigator-related reasons. Patient-related reasons include ethical issues such as the targeted patient needs to be hospitalised, is very ill, or there is a high mortality risk for patients. Investigators may not wish to subject these high-risk group of patients to the trial and thus would reject the study. Disease- or treatment-related reasons include investigational product (IP) containing pain-reducing capabilities but not disease-modifying action; IP has various drug-drug interactions and investigators are not confident with the IP mechanism of action in patients. Investigator-related refusal reasons include the transfer to a new hospital and away from work during the time when feasibility studies were conducted; these are reasons for them not being available to answer the feasibility assessments during that point in time, although they may be interested. In addition, insufficient time to answer the feasibility questionnaire within the timeline given (usually five working days) may also be a reason they refuse to participate in the feasibility assessment.

Conclusion

The results of this study showed that more than half of Malaysian investigators that were approached by CRM are interested in participating in clinical research. Similarly, this study also presented several key refusal reasons for investigators to participate in clinical research and the reasoning behind them. The interest of investigators is influenced by numerous factors, some of which are not intrinsic to the study protocol, yet invariably play a direct role in determining the uptake of the clinical trial. The reasons for refusal in feasibility assessments are important key points to consider when engaging with them in future feasibility studies, when implementing motivational interventions to encourage more investigators to participate in clinical research, and when developing frameworks and policies to support investigators' involvement in clinical research in the country.

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Impact of Strategic Alliance in Clinical trial Sites in Malaysia:

The ICR-CRM-IQVIA research network collaboration experience

Article published in Applied Clinical Trials, 1 October 2020

By Abdul Haq Nurhaizan (Alliance Manager, Clinical Research Malaysia), Joanne Yeoh (Clinical Operation Head of Department, Clinical Research Malaysia), Yong Li Fern (Associate Director, Patient & Site Services, SEA R&D Solutions, IQVIA) & Robert Kerle (Head of R&D Solutions, Southeast Asia, IQVIA)

Abstract

The success of a clinical trial is crucial in ensuring a drug is approved to be marketed and the process involves a significant amount of cost. The likelihood of a drug at Phase I making it all the way to the market tentatively has a 14% success rate.[1,2] Therefore, it is critical for pharmaceutical companies to ensure that the planning and implementation of a clinical trial strategy is effective in order to obtain the desired results. There are many factors which can contribute to the successful conduct of clinical trial; such as, the selection of high-quality clinical sites and complexity of the clinical trials protocol as it plays a major role in determining the successful rate of the clinical trial. However, the most important factor in determining the success of a clinical trial lies in the co-operation and teamwork of all the stakeholders involved, such as the pharmaceutical organization, the Contract Research Organization (CRO), the Principal Investigator (PI) and the clinical trial support team. This paper focuses on the impact of a Strategic Alliance (The ICR-CRM-IQVIA Network) in driving the Clinical Trial Sites in Malaysia. Pivotal success factors include enhanced site relationship, transparent communication channels, open information-sharing, and the on-going development of new processes and tools to overcome operational inefficiencies and challenges.

The likelihood of a drug at Phase I making it all the way to the market tentatively has a 14% success rate

Rationale for a relationship-based network

Regardless of the industry, business leaders agree that developing long term, mutually beneficial relationships, is critical to business success. Recognizing the importance of strategic alliance, ICR-CRM-IQVIA came into collaboration. The strategic alliance partnership of this Network is a site-centric, transparent, relationship-based commitment that empowers and facilitates operational improvements to clinical trials. Critical components, like tangible improvements to clinical trial operations between the stakeholders and the trial sites, are among the key success factors of this collaboration. In the context of strategic alliance, it can be defined as an agreement between firms to do business together in ways that go beyond normal company-to-company dealings but fall short of a merger or a full partnership.[3]

The establishment of Clinical Research Malaysia (CRM) was a key step by government of Malaysia to make country a Clinical Trial destination for sponsored clinical research.

ICR-CRM-IQVIA Network Stakeholders

Clinical Research Malaysia (CRM) is a provider of clinical research services that offers site management services to investigators conducting clinical research at hospital. The establishment of Clinical Research Malaysia (CRM) was a key step by government of Malaysia to make country a Clinical Trial destination for sponsored clinical research. CRM has a synergy team of approximately 130 trained Study Coordinators based at various sites conducting Industry Sponsored Research (ISR).[4] Institute of Clinical Research (ICR) functions as the clinical research arm of the Ministry of Health Malaysia (MOH) to support and facilitate activities in the MOH hospitals. In this collaboration, the major role of ICR is to support by providing trained and expert investigators and

site availability in order to coordinate Industry Sponsored Research (ISR)in MOH's Facilities.[5] IQVIA is a leading global provider of advanced analytics, technology solutions and contract research services to the life sciences industry. Formed through the merger of IMS Health and Quintiles, IQVIA applies Human Data Science – leveraging the analytic rigor and clarity of data science to the ever-expanding scope of human science – to enable companies to reimagine and develop new approaches to clinical development and commercialization, speed innovation and accelerate improvements in healthcare outcomes.

ICR-CRM-IQVIA Network in Malaysia

Since the collaboration that began in 2013, a network of sites has been established under the ICR-CRM-IQVIA network. In the beginning, 6 MOH Hospitals in Malaysia have been identified and selected to join the program based on rigorous criteria, among them the capability and capacity of the sites, and the commitment to operational efficiency and improvement. Currently, the network has now been expanded to total of 18 MOH Hospitals.

To ensure the success of the network in maximizing the research productivity, dedicated Alliance Managers (CRM & IQVIA) were assigned to manage the relationships and performance of these sites. The key success of the network is fundamentally about collaborative relationships to advance and accelerate science together for patients. Alliance Managers also act as ambassadors for their assigned sites, supporting business development and support system process improvement. The Alliance Managers maintain regular communication with assigned sites on:

- Developing close working relationships with site staff and in-depth knowledge of processes
- Project issues like enhancing recruitment through parallel channels for patients to access clinical trial
- Non-project issues such as overall site performance, contract timeliness, business strategy, mutual pipelines/planning to drive future growth.
- Close Monitoring Performance (Start-up Timelines, Patient Enrolment and Quality). KPIs are agreed upon collectively by the Joint Executive Steering Committee. Set up from the inception of the site alliance, these regular Joint Steering Committee meetings include shared discussions on study status, new studies, outstanding issues, forecasted deliverables (e.g., first patient enrolled), process alignment, and other topics.
- Initiatives to drive participation and productivity

It was that noted from the collaboration, that the performance of the clinical trial sites within this network have improved tremendously (from 2016 till 2019). Among them are:

- Significant increase in IQVIA's trial patient contribution from this network in Malaysia, 28% (2016) to 73% (2019).
- Significant increase in patient enrolment from this network from 2016 to 2019, increased 34% in patient numbers.
- Significant reduction in Contract Timelines from 2016 to 2019, with timelines reduced to 49%.
- Maintaining the Average and GCP Protocol Compliance at above 95%, with the increasing number of studies conducted at these sites from 2016 to 2019.
- Greater performance of clinical trial sites has also led to the increase in the number of clinical studies in Malaysia, yearly. This is in line with the vision of the alliance which is to establish Malaysia as a preferred destination for sponsored clinical research.

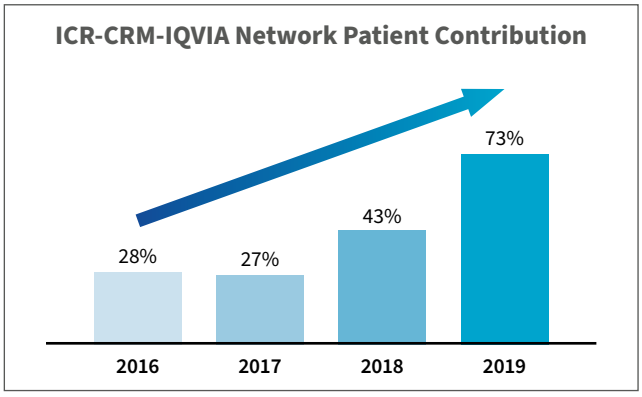

Figure 1: Percentage of Patient Contribution from ICR-CRM-IQVIA network sites into IQVIA managed studies in Malaysia.
Source data from IQVIA

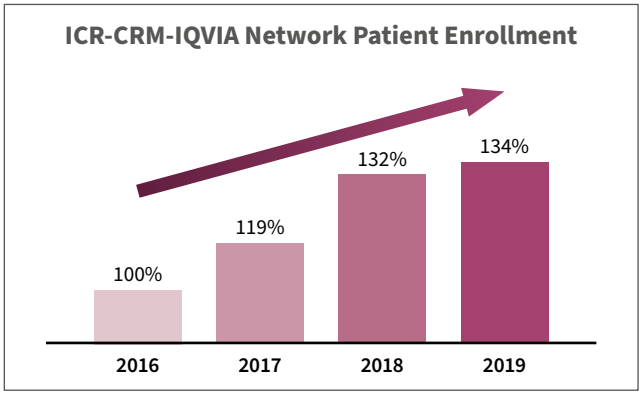

Figure 2: Percentage of Patient Enrollment of studies from ICR-CRM-IQVIA network.
Source data from IQVIA

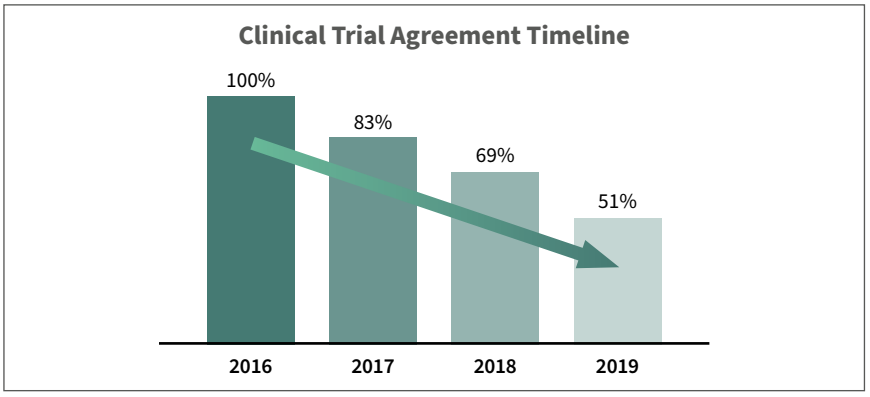

Figure 3: Clinical Trial Agreement Timeline (from initial draft to executed contract) of studies in ICR-CRM-IQVIA network.
Source data from IQVIA

In order for the strategic collaboration to sustain a competitive advantage in clinical trial, the network needs to be ready with more challenges for the future. Priority remains for the continued focus of the network to be the centre of excellence with successful achievement of the performance indicator. Maintaining the high performance is more challenging than attaining it.

It is clear that advancing technology and its integration in the way it implemented in clinical trials will be the focus in coming years. The network sites must be ready to embrace and adopt new clinical trial technology such as adapting electronic tools and methods in clinical trial activities. The network and its ability to generate and collaborate on innovative ideas rooted in the reality of clinical practice will be a critical partner in understanding where technology gaps are and how to best fill those gaps. For instance, there have been active discussions about remote, decentralized, and virtual trials especially in recent times. The required technology adaptions include and are not limited to electronic informed consent, telemedicine, electronic filing of study documents, etc. IQVIA has the ability to front this technology but would require support of CRM and ICR for successful implementation at the site level. CRM and ICR would have the critical role in evaluating the technology from a local perspective and in addressing the opportunities and possible limitations.

The network also needs to prepare forecasting the upcoming trends of clinical trials as it ensures that the strategic planning is aligned with the organisation goals. With such early preparation, the shift of the therapeutic area will not be a barrier for Malaysia to gain more studies.

The success of the clinical trial conduct proves that the importance of the strategic alliance's role for the sustainable competitive advantage and stimulate further conceptualization and research on the subject.[6] The advantage of the strategic alliance is not limited to the improvement of the organization performance, but it can also be a method for significant learning and knowledge acquiring, which eventually leads to sustainable competitive advantages for all partners. Regardless of the challenges ahead, what is definite is that relationships are the foundation upon which this network is built on and the strength of this network will continue in sustaining it long into the future.

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CRM IN PHOTOS

Meeting with National Science Council at the Parliament

15 Jul

Meeting with Dr Khor Swee Kheng (Health Systems/ Policies/Health practitioner)

6 Aug

Meeting with Cytonex Sdn Bhd

19 Aug

Meeting with Embassy of Russian Federation in Malaysia

26 Aug

Dr Goh Pik Pin Retirement

28 Aug

Meeting with Deputy Director of Life Sciences & Medtech Division of MIDA

2 Sep

Virtual Nurturing New Talent in Sponsored Research– East Coast

10 Sep

Meeting with Mr Isaac Lim and Ms Alicia Tee from Singapore High Commission

11 Sep

Meeting with Meluha Life Sciences

17 Sep

Courtesy visit by Deputy Trade Representative of Russian Federation in Malaysia

18 Sep

Provisionally Registered Pharmacist (PRP) attachment

22 Sep

Meeting with Tri-G Technologies Sdn Bhd

25 Sep

Meeting with Navamed

30 Sep

Meeting with GHHS Healthcare

1 Oct

Meeting with Future CytoHealth

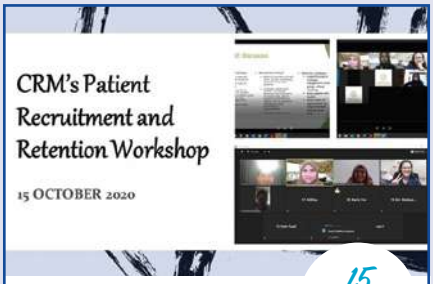
6 Oct

Client Engagement Meeting with Janssen

7 Oct

Training to Improve Performance of Study Coordinators

14 Oct



CRM's Patient Recruitment and Retention Workshop

15 Oct

Awareness Briefing Session for ISO 37001:2016 Anti-Bribery Management System

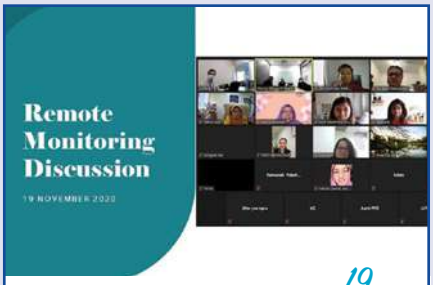
22 Oct

Preparation of Regulation Inspection Workshop

23 Oct

MREC Good Submission Practice Training 2020

3 Nov



Remote Monitoring Discussion

19 Nov

2nd GCP Refresher Workshop 2020

23 Nov

CRM 4th Company Meeting 2020

1 Dec

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