BY CLINICAL RESEARCH MALAYSIA

CRM Bulletin

ISSUE 23 | Jan - Jun 2022

A DECADE OF DRIVING CLINICAL RESEARCH

RESEARCH PERSONALITY
DR MUTHUKKUMARAN THIAGARAJAN

FEATURED SITE
HOSPITAL TUANKU JA'AFAR

RISING STARS IN ONCOLOGY

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.

10TH ANNIVERSARY
CRM
CLINICAL RESEARCH MALAYSIA
10 Years of Global Solutions in One Nation

From The CEO's Desk

Clinical Research Malaysia is proud to present the first bulletin issue in 2022, Issue 23!

Last year, we witnessed outstanding achievements for sponsored clinical research in the country, with the highest number of sponsored trials recorded in Malaysia (215 sponsored studies), compared to the years before. In addition, Malaysia now ranks the 2nd highest in the region, amongst other Southeast Asian countries, in number of sponsored trials awarded. Just up to June of this year, Malaysia has had 106 approved trials, generating over RM 65, 000, 000 in Gross National Income (GNI). With these amazing accomplishments, we have much more to look forward to this year.

It is a special milestone in CRM this year, as we mark CRM's 10 years of delivering studies with speed, reliability and quality, as a globally trusted organization. It has been a bustling first half of the year, with the opening of international borders and the transitioning of many activities from virtual to hybrid and physical presence. CRM has re-initiated its in-person participation in international engagements. In June, we had conducted industrial engagements in Geneva, along with the presence of the Minister of Health. We were also present in the ASCO Annual Meeting which was held in Chicago and will soon be attending ESMO Congress in Paris to build network and promote Malaysia as a destination for global sponsored research. At the local front, we have held our first physical I AM AWARE public awareness roadshow in 2 years at the National Cancer Institute, Putrajaya, in conjunction with the Clinical Trials Day celebration in May.

With the completion of Phase 1 Realization Program (P1RP) in end of 2021, CRM has initiated P1RP 2.0 to further strengthen current capabilities in Malaysia's early phase landscape and address current gaps in First-in-Human study conduct in the country. Through P1RP 2.0, CRM hopes to expand Malaysia's Phase 1 ecosystem by providing early phase specialization opportunities for regulators, investigators and study coordinators in Malaysia. CRM will also facilitate in the accreditation of Institute Kanser Negara (IKN) as a Phase 1 Unit.

Most importantly, we are looking forward to conducting the very first Trial Connect Conference this coming October, which is aimed to showcase Malaysia's experience and achievements in global clinical trials. We look forward to especially engaging and networking with industry members and investigators during this program. Finally, I'd like to express my sincere gratitude to everyone in CRM for their continuous support in making Malaysia the preferred destination for sponsored research over the past decade. We have come a long way and it would not be possible without the effort from everyone within CRM and our working partners.

Thank you for being a part of CRM's journey and letting us be a part of yours. We look forward to creating a greater impact this year!

Dr. Akhmal Yusof
CEO, Clinical Research Malaysia

www.clinicalresearch.my

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HIGHLIGHTS

Nurturing New Talents in Sponsored Research

17 February & 25 May 2022 – CRM successfully conducted two Nurturing New Talents in Sponsored Research seminar virtually, with the later seminar done in collaboration with B Braun. This seminar is conducted in aims of driving interest and growing investigator pool in clinical research.

GCP Refresher Workshop

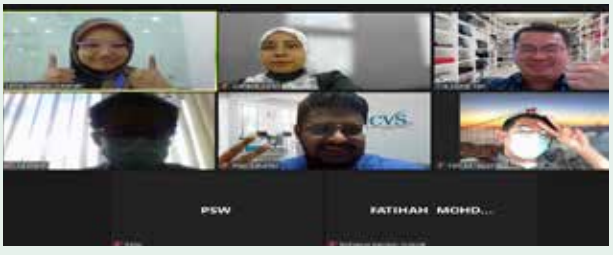
16 March & 22 June 2022– CRM carried out 2 GCP Refresher workshops in the first half of the year, pivoting around informed consent and investigational product management respectively.

CRM Board of Directors Meeting

21 March 2022 – CRM held its first Board of Directors meeting in 2022, chaired by the Minister of Health, YB Khairy Jamaluddin. The board members were presented with the 2021 sponsored clinical research data which recorded the best annual performance since CRM's inception.

CRM National Conference 2022

24 March 2022 – This year, CRM conducted its Annual National Conference via a virtual platform. In light with CRM's 10th anniversary, Dr Akhmal shared the achievements, goals & opportunities in CRM to all employees. During the program, the CEO Awards and Long Service Awards were also presented to deserving employees, in recognition of their outstanding achievements.



Patient Recruitment and Retention Workshop

26 March 2022 – CRM successfully conducted the patient recruitment and retention workshop, sharing on potential challenges and overcoming recruitment hurdles while complying to regulatory requirements. Attendees include specialists, research officers, pharmacists and study coordinators involved in clinical studies.

TIPS training

18 May (ARM); 22-30 May & 1 June 2022 (Study Coordinators)
CRM has just completed Part 1 of TIPS (Training to Improve Performance of Study Coordinators), themed 'Back to Basic'. Conducted annually, the TIPS program is part of CRM's continuous training and development program for ClinOps team, in ensuring best clinical operations practices at study sites managed by CRM.

Client Engagement in Geneva

27 May 2022 - Minister of Health & CRM Chairman, YB Khairy Jamaluddin, had met with several key pharmaceutical representatives during his working visit in Geneva, including Stalicla & Beigene. Discussions during the meet was focused on bringing in more trial opportunities into Malaysia, and the country's value proposition of genetic diversity and delivery of studies with speed, quality and reliability as an attractive factor for global sponsors.

ASCO Annual Meeting 2022

3 - 7 June 2022 – CRM participated for the first time in the ASCO Annual Meeting 2022, which was held in Chicago, US. The team met up with industry leaders in the field of oncology during the program, building new connections within the clinical research fraternity & promoting Malaysia as a destination for sponsored research to global sponsors and CROs.

CRM Turns 10!

15 June 2022 – This year marks the 10th year of Clinical Research Malaysia in operations. CRM was established on June 15, 2012, by the Ministry of Health to make Malaysia the preferred destination for clinical research. In conjunction with CRM's 10th year anniversary, CRM is preparing many exciting activities. Just in May, CRM's 10-anniversary logo was launched and CRM is preparing for an expedition to climb Mount Kinabalu in conjunction with the 10th anniversary and is in the midst of preparing its very first Trial Connect Conference. CRM looks forwards to many more years of success.

Investigator Dialogue

23 June 2022 – CRM had its annual Investigator Dialogue with regulatory representatives from MREC & NPRA and CRM representatives themed '10 years together and beyond, advancing in global clinical trials'. During this dialogue, latest updates and the future direction of clinical research was shared and discussed.

IN THE NEWS

Malaysia Outperforms Its Achievement In Sponsored Clinical Research

PUTRAJAYA, 21 March 2022 – CRM's Annual Report 2021 was launched by the Minister of Health, YB Khairy Jamaluddin at the Ministry of Health complex in Putrajaya, witnessed by CRM Board of Directors and stakeholders. The annual report outlined clinical research's outstanding performance in 2020, with 215 new sponsored clinical research in the country, the highest annual number reported since CRM's inception. In 2021, Malaysia moved a position up, now ranking second within Southeast Asia region after Singapore, in terms of the number of global industry sponsored studies.

The Gross National Income also reflected these record-high numbers, with highest annual value of RM 226 million investment reported from new sponsored studies, contributing to a cumulative value of RM 834 million generated from sponsored research since 2012.

During the event, the Phase 1 Realisation Project (P1RP) Report was also unveiled, wrapping up the five-year initiative which began in 2016. The P1RP was developed by CRM with the support of the Ministry of Health, mainly to ensure readiness of Malaysia's clinical research ecosystem for safe and quality conduct of early phase research, especially First-in-Human (FIH) studies.

With this project, Malaysia has successfully setup a Phase 1 guidelines, established a Phase 1 accredited facility in Sarawak General Hospital (SGH), and conducted its very first, First-in-Patient study in 2021. In addition, CRM had also sponsored the training and development of three National Pharmaceutical Regulatory Authority (NPRA) officers as well as Dr Voon Pei Jye, a medical oncologist from SGH, in their completion of postgraduate studies and fellowship respectively, centered on early phase research.

With the conclusion of P1RP 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.

Ministry Of Health And Drugs For Neglected Diseases Initiative (DNDi) Combine Forces To Lead The Battle Against Dengue

KUALA LUMPUR, MALAYSIA, 29 April 2022 – Malaysian Ministry of Health through Clinical Research Malaysia (CRM) will be collaborating with Drugs for Neglected Diseases initiative (DNDi), an international non-profit medical research organization, in aims of developing safe, affordable, and effective treatments for dengue fever.

Malaysia joins a global dengue partnership led by dengue-endemic countries to conduct preclinical studies and clinical trials through this agreement to delivering affordable and accessible treatments within the next five years. The collaboration focuses on a drug repurposing program, where Malaysia along with research institutes Fiocruz (Brazil), THSTI (India) and Siriraj Mahidol University (Thailand) will be investigating on 23 identified compounds for potential repurposing as dengue treatment.

In Malaysia, major research institutes such as Institute for Clinical Research (ICR) and Institute for Medical Research (IMR) will be participating in this project, to progress preclinical and clinical investigations of potential treatments. At the same time, it will coordinate efforts to help overcome knowledge gaps and expedite clinical research to address unmet needs. The partnership will work together to mobilize resources, share research knowledge, and address financing gaps.

Tribute To Clinical Research Stakeholders In Celebration With Clinical Trials Day

PUTRAJAYA, 19 May 2022 – Clinical Research Malaysia (CRM) celebrated International Clinical Trials Day with the Deputy Minister of Health I, Dato' Dr. Haji Noor Azmi Bin Ghazali as well as stakeholders within the clinical research industry in Malaysia.

With this year's theme 'Get Involved', the CRM's Clinical Trials Day celebration was celebrated in commemoration for the tribute clinical trial volunteers, investigators, study team members, regulators as well as industry members who have supported the clinical research ecosystem in Malaysia.

CRM's I AM AWARE Photography series was also showcased during the event, highlighting the bona fide journey of trial volunteers. Additionally, several industry members exhibited their latest research activities and developments during the program.

CRM also initiated its 10th-anniversary celebration during the event, with the launch of the 10th year logo, celebrating the decade milestone of supporting sponsored clinical research in the country. In 2020, CRM achieved its formation objectives and have paved multiple collaborations and partnerships with global partners in further enhancing the development of sponsored research within the nation.

CRM Sponsored Research Awards 2022

CRM Sponsored Research Awards (SRA) is presented annually to recipients who have contributed significantly to sponsored clinical research in Malaysia. Usually presented during the Clinical Trials Day celebration, the SRA awards tributes the accomplishments of investigators, study team as well as industry members for the good work led in growing sponsored clinical research in the nation.

This year, eight SRA awards were presented during the annual Clinical Trials Day celebration by Dato' Dr. Noor Azmi, on behalf of the Minister of Health.

Top Recruiter Award
Dr Vijaya Kumar Suppan (Hospital Sultan Abdul Halim)
for achieving the highest number of subjects recruited in studies conducted in 2021.

Significant Advancement Award (Site)
Hospital Miri
Top infectious diseases study site in the country, and in marking significant growth in number of studies conducted as well as study value contracted, compared to the years before.

Investigator of the Year Award
Associate Professor Dr Lim Soo Kun (University of Malaya Medical Centre)
for being among top Principal Investigator with high number of new sponsored research in 2021, in addition to co-authoring in a publication for a multinational study

Significant Advancement Award (Investigator)
Dato' Dr Fam Tem Lom
for demonstrating significant increase in number of sponsored studies in 2021, which includes active participation in conducting Covid-19 treatment studies.

Top Study Site (Overall) Award
University of Malaya Medical Centre
for having highest number of studies awarded in 2021, as well as being top oncology and infectious diseases study site.

Sponsor of the Year Award
Merck Sharp & Dohme
for contributing highest cumulative study value in 2021 and among top sponsor for new studies of 2021.

Top Study Site (MOH) Award
Hospital Pulau Pinang
for being among top MOH sites in number of studies awarded in 2021 and for contracting highest study value among MOH sites in 2021.

CRO of the Year Award
IQVIA RDS Malaysia Sdn Bhd
for contracting highest cumulative study value in 2021, and among top CROs in 2021 for new studies.

RESEARCH PERSONALITY

Dr Muthukkumaran Thiagarajan

Clinical Oncologist at Department of Radiotherapy and Oncology, Hospital Kuala Lumpur

About Dr Muthu

Dr Muthukkumaran graduated in 2004 from Universiti Putra Malaysia with double degree programme of B.Sc. (Medical Sciences) in 2002 and Medical Doctor degree. He served as a house officer and medical officer in Hospital Tawau, Sabah. Dr Muthu was then stationed in Hospital Likas, Kota Kinabalu under Dr Jayendran Dharmaratnam, who set up the oncology services in Likas. He subsequently pursued his postgraduate degree in Clinical Oncology at University of Malaya, which he completed in 2012. After completing his gazettement, Dr Muthukkumaran was initially posted to Kota Kinabalu, and since 2015, has been back in Hospital Kuala Lumpur.

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

My first exposure to medical research was in medical school, whereby it was compulsory for us to produce a thesis to qualify for the B.Sc. degree. My supervisor then, Prof Dr Johnson Stanslas, who still serves in Universiti Putra Malaysi,a was truly instrumental in inspiring me into the research culture. I was involved in a translational research looking into chemosensitivity of leukemic cells isolated from bone marrow specimens of children undergoing diagnostic workups. Part of this research project was later published as a case study.

Have clinical trials changed your practice and management of patient care?

Oncology is an ever-expanding and developing field. As we do not have a reliable “cure”, the hunt is constant in search of the best remedy. Therefore, research is part of the subject matter. Our daily clinical decisions are based on best evidence available from clinical studies and publications. Consensus guidelines are based on extensive literature review of past and on-going research.

What are your challenges when conducting clinical trials?

Space to conduct clinical research is probably the main challenge in Hospital Kuala Lumpur. The design of the building where I am based was conceptualized in 1970s, so it is quite incompatible with our current working pattern. Through partnership with National Cancer Centre in Japan through the ATLAS project, a space within the department has been secured as a dedicated clinical trial unit. It is a small step, and hopefully such partnerships will open up more avenues to develop clinical trial related facility and expertise in the future.

What drives you to conduct clinical trials?

Clinical trials impact future clinical practice and change the viewpoint that exists in the current practice scenario. I am truly motivated to be part of such changing paradigm.

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

Rewarding. It is mindfully rewarding to be able to provide access to latest treatment options to patients. It is rewarding to the clinical practice in gathering experience of using latest oncology therapies.

Where do you wish to see in Malaysia, in the field of clinical research in the future?

Malaysia has the potential to be a research hub for clinical trials and research. We are an attractive option for global sponsors, where we are sought as recruitment sites for multinational trials. This in turn would open access for our own Malaysia's translational research to develop further, especially in pairing strategic sites in conducting clinical studies for locally developed therapies. Research culture should be ingrained in every department within all hospitals here.

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

There is a need for development of human resources for the purpose of clinical trials. We have struggled with this for quite some time, and thanks to the support from Clinical Research Malaysia, Clinical Research Centre HKL and Ministry of Health (MOH), we now have adequate staff within the department to conduct multiple clinical trials simultaneously. Other sites are probably not as fortunate as us in HKL, and therefore this should be made a focus.

There is also a huge need for developing of a dedicated facility within each major hospital to conduct research. This facility should include an administrative officer, researcher's office, study coordinator's office, clinical trial space for patients, storage space for investigational products, equipment storage, consumables store, laboratory and so on. A comprehensive one-stop centre to conduct research will be highly efficient in busy centres for a smooth research experience, and serves as a good base to train more personnel.

MOH is primarily concerned about clinical service, and hence, the research is mainly left to the universities. Such dichotomy should no longer exist as research transcends all walks of medical practice. If the ministry could devise a plan to reward medical doctors who are researchers, it will significantly help boost up the interest. Rewards could be a time-off to conduct trials, monetary rewards, recognition and even a promotion.

Dr Muthukkumaran in his office

Standing (L-R): Nur Syamimi Binti Rosni, Anis Hazirah Binti Asmali Jauhari, Masyitah Hasan, Sri Ratha Balakrishnan, Hanani Binti Che Halim, Faizah Binti Mohd Hanapiah, Norfarahin Binti Badrul Hisham & Amirah binti Mohamed Tahir (CRM Study Coordinators)

> **"It is mindfully rewarding to be able to provide access to the latest treatment options to patients"**

RISING STARS IN ONCOLOGY

With over 1800 sponsored trials since 2012, Malaysia has demonstrated the ability in conducting trials involving various therapeutic areas. To date, SGH (Sarawak General Hospital) has participated in over 80 sponsored oncology studies, many of which were Phase 3 studies followed by Phase 2, Phase 1, and Phase 4 studies. Dr Voon Pei Jye, the head of SGH's oncology department is committed in further growth of Malaysia's capabilities in conducting trials, especially in early phase studies. In this light, Dr Voon has been guiding and developing oncologists in SGH to further encourage the conduct of high-impact sponsored trials in Malaysia. In this issue, CRM would like to highlight the rising oncologists from Sarawak General Hospital to share their experience as PI in sponsored trials in Malaysia.

Dr Lim Yueh Ni
Clinical Oncologist

Department of Radiotherapy, Oncology and Palliative Care
Sarawak General Hospital

My beloved aunt was diagnosed with breast cancer Stage IIIC when I was still studying in medical school. Our family were in fear of losing my aunt within a short period of time. However, fortunately she survived for another good 7 years after receiving anti-cancer treatment. Our whole family really treasured those 7 years together with my late aunt as it was her 'second life'. She was blessed to have extra time to fulfil her dreams. Hence, I chose to specialize as an Oncologist, with the aim to improve the survivorship and quality of life of cancer patients.

By conducting clinical trials, I could understand how the clinical data were acquired and derived. I learn study details of clinical papers and interpret the results from a more clinically relevant aspect. I also gain experience of using new medications and managing its adverse events from reading through the serious adverse event reports from different countries. Despite gaining the opportunity for self-development, the main drive for me to be involved in clinical trial is improving the accessibility of novel targeted agents for our cancer patients in government hospitals.

Dr Ngu Ming Ruey
Clinical Oncologist

Radiotherapy & Oncology Sarawak General Hospital

I was first involved in clinical trials when I was a postgraduate trainee in Clinical Oncology. I had the opportunity to be involved in oncology trial and gained experience as a sub-investigator. It changed my perspective as to see how much difference clinical trials can change the course of treatment for patients, other than the conventional clinical service. I became more involved in clinical research during my work as a clinical oncologist in Sarawak General Hospital.

Cancer care is my main research interest and passion. Being able to contribute and being part of research teams to find better ways to treat cancer, motivates me to be involved in clinical trials as it improves patient care by gaining access to new and possibly effective treatments. Clinical trials have always been important to the development of new agents and interventions and oncology is one of the most rapidly growing clinical fields with new evidence changing treatments standards every year.

I would recommend my peers to take up clinical research. Clinical trials are important as it might change clinical practice and improve outcomes. We should provide our patients with the best treatment care options and clinical trials give access to patients to expand their treatment options.

Dr Heng Fook Yew
Clinical Oncologist

Sarawak General Hospital

My participation in clinical research started during clinical oncology training at University Malaya. Since then, my priority has changed to now, making sure patients under my care get the opportunity to participate in available trials if they meet the required study criteria. In addition, by adhering to the clinical trial protocols, I was able to match my practice on par with international standards, as well as ensuring our local practice does not differ much with what other countries are doing especially in the developed nations.

Participation in clinical trials allow patients to received up-to-date treatment at zero cost. As we are aware of financial toxicity in cancer care, clinical trials provide the platform for limited income patients to received latest treatment. At the same time, investigators are able to gain experience using trial medications.

Dr Hadi bin Ab. Jalil
Clinical Oncologist

Sarawak General Hospital

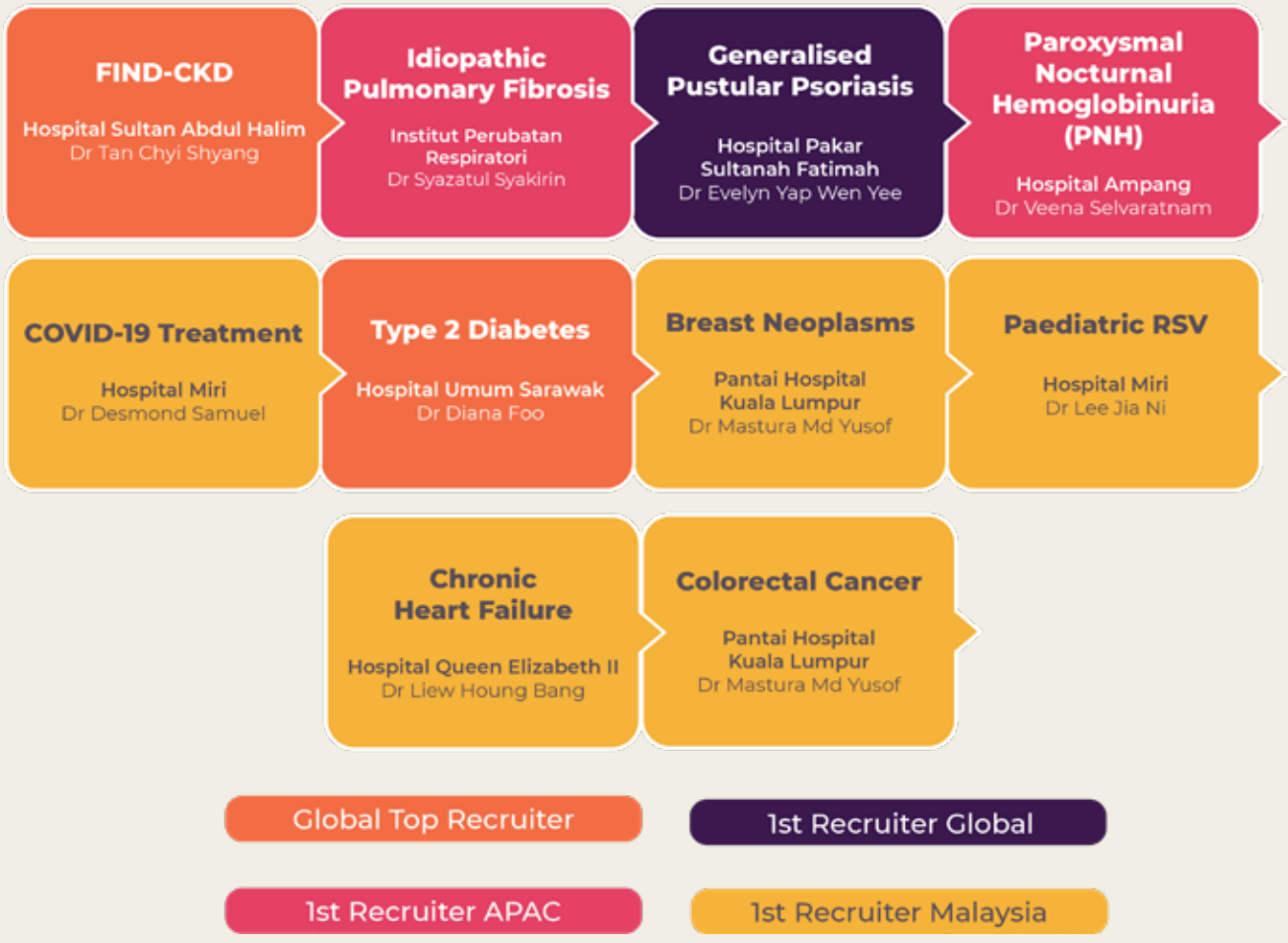
My primary research plan is aimed towards the less common cancer diseases that will benefit the community. Lacking in subsequent line of treatment in less common cancer type limits the options and that translate into poor survival. Thus, embarking into the less common type of cancer may help the community to achieve the primary goal which is prolonging the survival. There have been many people that have influenced me to venture into this field. It started during my undergraduate years until now, my career as a clinical oncologist. These people have affected my character which stimulate an intense curiosity regarding scientific explanation of how the disease and treatment is related. From then onwards, I started to realize, being a physician researcher is the way to solve my curiosity.

The career of being a physician researcher is unique. There are few comparable careers that allow one to experience the passion of solving a patient's medical struggles while pursuing research that may define the mechanism of that patient's disease and may ultimately translate into clinical cure for the disease. Experience in research setting is invaluable. Exposure to an area of research undoubtedly helps one to explore sub speciality fields. Furthermore, research is performed in teams, and we have to learn to balance the collaborative effort rather than accomplishing independently.

INFOGRAPHIC

RECRUITMENT ACHIEVEMENTS IN GLOBAL SPONSORED RESEARCH 2022

January - June



ROADMAP TO BECOMING AN INVESTIGATOR

01 Specialist

Are you a specialist in your area of expertise?

Often consultants or specialists who are sought for to conduct clinical trials.

02 GCP

QUALIFICATION

Undergo Good Clinical Practice (GCP) training and pass the GCP examination.

Usually organised by CRCs at MOH hospitals and by universities.

03 Register

Register your interest to be an investigator with the hospital CRC and CRM.

Approval and support from your department are especially important in your journey to being an investigator.

04 Study Team

PARTICIPATE

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

05 Perform

EXPERIENCE

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

06 Feasibility

Experienced investigator will be approached by CRM for new feasibility studies.

Questionnaires provided would need to be answered accurately within the timeline agreed.

07 Evaluation

Sponsor or Contract Research Organization (CRO) will approach site & investigator for further evaluation if post-feasibility assesment is successful

08 PI

START UP

Awarded as Principal Investigator (PI) for site or study if selected.

CRM will facilitate PI for study budget and Clinical Trial Agreement review during study 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*

CRM
CLINICAL RESEARCH MALAYSIA
Your Global Solutions in One Nation

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

CRM NEW SERVICES

CRM TRIAL CONNECT

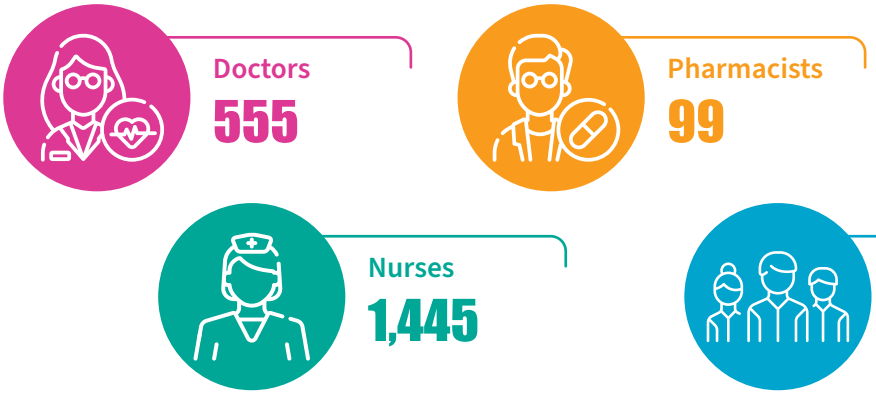
FEATURED SITE

Hospital Tuanku Ja'afar, Seremban

Hospital Tuanku Ja'afar Seremban (HTJS) is located at Jalan Muthu, off Jalan Rasah, Seremban. It is the largest and leading referral hospital in Negeri Sembilan with facilities including Ambulatory Care Complex and Women and Child Complex. The hospital has a capacity of approximately 1143 beds with 19 clinical specialty services which serve 24 hours a day, and seven days a week.

HTJS provides secondary and some tertiary level of care through various settings:
- Specialist inpatient care
- Specialist outpatient and emergency care
- Ambulatory care
- Teaching and research activity

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



Numbers of population served: 1,199,974 (Negeri Sembilan population by Jab. Statistik Malaysia 2020)

The secondary and tertiary level care services available are as listed below:

General Medicine
- Endocrinology
- Rheumatology
- Haematology
- Palliative care
- e. Geriatric Medicine
- Infectious Disease
- Gastroenterology
- Respiratory Medicine
- Neurology

General Surgery
- Colorectal Surgery
- Paediatric Surgery
- Neurosurgery
- Plastic surgery (visiting)
- Urology (visiting)

Orthopaedics
- Advanced Trauma
- Sport Medicine

Obstetrics and Gynaecology
- Fetomaternal
- Reproductive Medicine
- Urogynaecology
- Gynae-oncology

Paediatric
- Nephrology
- Infectious Disease
- Neonatology
- Respiratory Paediatric (visiting)

Ophthalmology
- Vitreo – Retinal

Otorhinolaryngology
- Otorhinoneurology
- Paediatric Otorhinolaryngology (visiting)

Anaesthesiology
- Adult Intensive Care
- Pain Service
- Paediatric

Psychiatry and Mental Health
- Community Psychiatry
- Psychogeriatric
- Child Psychiatry (visiting)

Emergency and Trauma
- Paediatric Emergency Medicine

Pathology
- Haematology
- Histopathology
- Cytology
- Microbiology
- Chemical Pathology

Dermatology

Rehabilitation Medicine

Oral Maxillofacial Surgery

Paediatric Dental

Nephrology

Radiology

Transfusion Medicine

Forensic Medicine

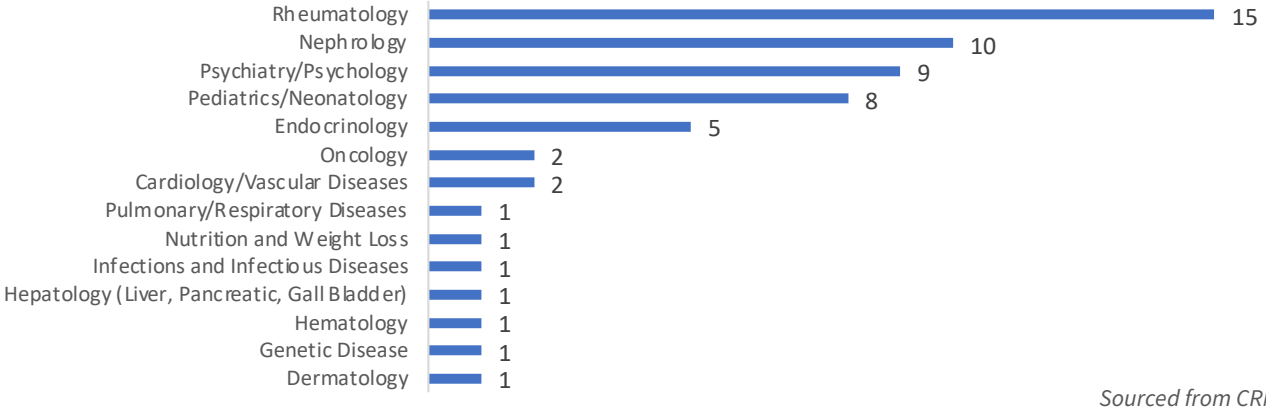
Clinical Research Centre, HTSJ

Clinical Research Centre Hospital Tuanku Ja'afar (CRC HTJS) was established in September 2006. It is one of the 37 centres under the network of Institute for Clinical Research (ICR), set up under the National Institute of Health. The CRC network was established in line with the vision and mission of Ministry of Health; to make research one of the important key activities at Ministry of Health. The CRC HTJS serves as a local coordinator centre for research activities, clinical registry and training related to research. It is located at Level 2, Specialist Clinic Complex Hospital Tuanku Ja'afar.

CRC HTJS Facilities




Numbers of sponsored studies conducted in HTSJ based on therapeutic areas (2012-2021)



Sourced from CRMx

Clinical Research Achievements

2015 – 2017: Brilliant (Top Recruiter Q4 2016, Q2 2017) - Transdermal Antipsychotic

2015 – 2017: Brilliant (Top Recruiter Q4 2016, Q2 2017) - Psoriatic Arthritis

2018: 54135419SUI3001 (Exceeding Site Recruitment Target) - Major Depressive Disorder

2020: CAIN (First Patient, First Visit in Malaysia) - Psoriasis

2021: 54135419TRD3013 (First Subject Randomized in APAC Region) - Major Depressive Disorder

2021: CMIJ821A12201 (First Patient in Malaysia) - Major Depressive Disorder with Suicidal Ideation with Intent

2021: 42847922MDD3005 (First Patient in Malaysia) - Major Depressive Disorder

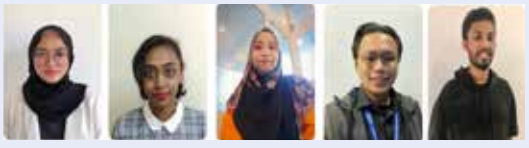
2021: TRACK (First Patient in Malaysia) - Oncology

CEO AWARDS 2022

The distinguished CRM CEO Awards is presented annually to deserving CRM's employees, in recognition of their outstanding achievements the year before. The awards also serve up as a motivation to CRM employees to perform and excel in their given role.

In 2022, a total of four awards were handed out to individual and teams that have excelled in the projects undertaken. The awards were presented during th CRM National Conference in March 2022

High Work Performance & Good Work Ethics
Adibah Hamiza Binti Ahmad Suhaimey



Project/Work Title
Sports & Recreational Committee - Creativity in virtual SRC activities

Siti Khadijah Sakaria, Sathiavani Arikrishnan, Nor Sakinah Mohd Jamian, Muhammad Amin Hafiz & Sivanesan S. Seevagan

Project/Work Title
SGH Team - Site Model

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Project/Work Title
ISO Team - Recertification of ISO 9001:2015 and Certification of ISO 37001:2016

Komala Pannir Selvam, Sarena Hasniza Shamshuddin, Asha Thanabalan, Nurul Atiqah Abd Rahman, Norazua Dahlan, Nor Hafiza Johari, Intan Munirah Mohd Murad, Tan Sia Hong & Harnani Tamat

Project/Work Title
ISO Team - Recertification of ISO 9001:2015 and Certification of ISO 37001:2016

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Growing the Pool of Clinical Research Investigators in Malaysia

Article published in Journal for Clinical Studies, Volume 14, Issue 2

By Nur Ain Amir, Cheng Shu Hui & Audrey Ooi; Clinical Research Malaysia

Introduction

The Malaysian government has continuously strived to improve and expand its clinical research ecosystem for the past ten years. The primary goal is to provide a competitive landscape with internationally recognised clinical trial hubs as more pharmaceutical companies continue shifting their clinical trial bases to Asia.

One of the strategies implemented with success by the Malaysian Ministry of Health (MoH) is the establishment of Clinical Research Malaysia (CRM). CRM is a non-profit company acting as a "one-stop" centre to facilitate the growth of industry-sponsored research (ISR). Since the launch of CRM in 2012, it has successfully closed the various gaps within the clinical research ecosystem and continues to address and improve existing unmet needs.

Since early 2000's, Asia Pacific has seen the benefits of increasing interest by pharmaceutical industries in conducting clinical trials in the region. The cumulative volume of clinical trial densities of selected countries in the South East Asian (SEA) region has almost tripled from 2016 to 2020.1,2 The clinical trial density in Malaysia doubled from 2016 to 2020, i.e. from 8 to 17, and this is reflected in the increasing numbers of ISRs conducted in the country.1-4 The number of sponsored research conducted in Malaysia is growing steadily from 162 studies in 2019, 191 studies in 2020 and 215 studies in 2021 despite the COVID-19 pandemic.3,4 A crucial aspect in conducting high quality clinical trials is the availability of qualified and experienced investigators. Hence, Malaysia will need to increase the pool of available clinical investigators to match the demand and interest of sponsors and contract research organisations in conducting trials here. This article focuses on the current status of Malaysian investigators and the future perspectives for CRM and the MoH in growing the country's clinical investigators pool.

Global Perspectives on Principal Investigators (PI)

Although the day-to-day tasks of a clinical trial are performed by various study team members, PI is pivotal in ensuring the proper conduct of the clinical research and patient safety.5

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH E6) Good Clinical Practices (GCP) details the roles and responsibilities of clinical research investigators, including that of the PI.6 All investigators must be GCP certified and have experience in conducting quality trials. Investigators need to demonstrate the ability to recruit the targeted subjects, supervise and complete the trial within the study timelines, as well as to train the support staff. The investigator and institution (clinical trial site) must ensure there are adequate medical facilities to support the clinical trial, especially when adverse events caused by the investigational product occur.

The number of PIs worldwide varies widely depending on the source of information.7 Separate databases set up by different clinical research organisations (CROs) and clinical trial organisations estimate between 40,000 to 500,000 PIs globally. Some of these databases reveal that the largest proportions of PIs are in Europe (40%) and North America (32%). Asia- Pacific has the third-highest proportion at 18%. Based on the ClinicalTrial.gov and the DrugDev network databases, an investigator engages with one to three trials per year on average.7 The IMS Health database, however, shows that 32% of investigators undertook only one trial in five years.7

Clinical Studies in Malaysia

The Malaysian healthcare system encompasses healthcare facilities under three large categories, i.e. the MoH, the Ministry of Higher Education (MoHE; that includes teaching hospitals) and the private sector. Clinical trials can be conducted in any healthcare facility within the three categories provided they fulfil the regulatory and ethical criteria set by the Malaysian GCP, as well as local regulations and guidelines. From 2017 until 2021, the majority of sponsored research studies were conducted in the MoH public hospitals and health clinics, followed by the MoHE teaching hospitals (Figure 1).4

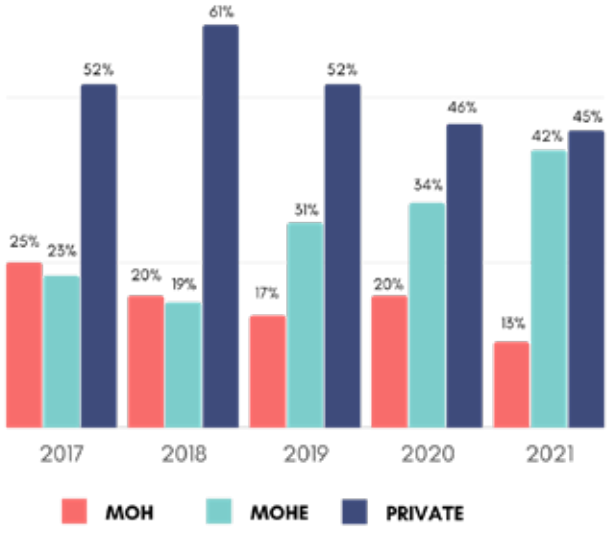

Figure 1. The percentage of approved sponsored research conducted in the three healthcare systems in Malaysia. 4

Note: For multi-centre studies, the same trial could involve multiple sites from different sectors. However, only a single value will be captured under the site sector, irrespective on the number of site(s) within the sector

The extensive utilisation of the MoH and MoHE hospitals as clinical trial sites is not surprising. Though there are 45% more private hospitals than public hospitals in Malaysia,8 the official bed capacity is 260% more in public hospitals. The vast difference in the patient population can also be seen in the number of admissions and outpatient attendance between the two healthcare sectors. The public sector has approximately twice the number of admissions (2.3 million vs 1 million) and seven times more outpatient attendances (21.4 million vs 3 million).8 The major reason for such high patient volumes in the public sector hospitals is that patient management is heavily subsidised by the government. At a nominal fee, patients receive consultation, investigations and treatments for all minor and most major conditions/disease. Hence, the patient capacity and potential subject recruitment are significantly higher within the public hospital setting.

The Need for More Clinical Investigators

In 2018, there were 11,686 registered specialists in Malaysia from both the public and private sectors and across various specialities.9 The public hospitals held more total specialists (58.4%) than the private sector (41.6%).

The majority, if not all, of the PIs conducting clinical research are specialists, and the top five number of new ISRs by therapeutic areas between 2015-2021 were oncology, cardiology, infectious disease, endocrinology and haematology (Figure 2).4 In 2020, there were a total of 300 cardiologists and 133 oncologists, of which only 10% and 26% were working in the MoH hospitals, respectively.10 Not all specialists have received Good Clinical Practice (GCP) training and are experienced in conducting or leading clinical trials. Therefore, the discordance created between the number of available specialists and principal investigators as well as the growing number of clinical trials in the top 5 therapeutic areas indicate the pressing need to grow the pool of investigators, especially in those mentioned therapeutic areas. These gaps have led to current investigators being saturated with conducting clinical trials and thus a limitation with accepting more ISRs, and the opportunities to explore new treatment for the population.

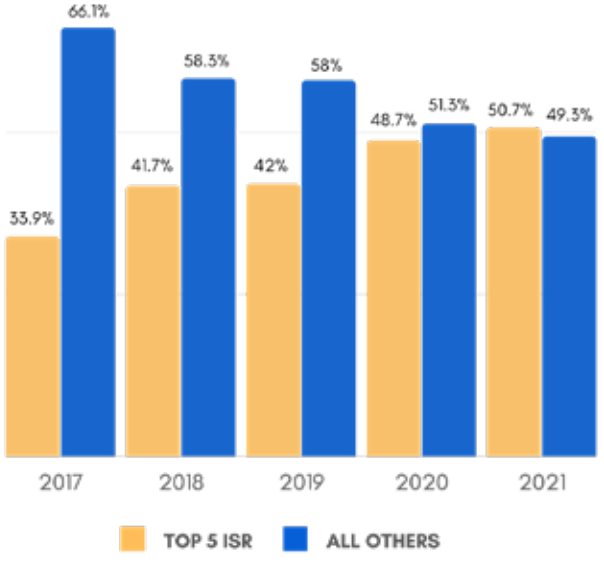

Figure 2. Proportion of the top five ISRs based on speciality (oncology, cardiology, infectious disease, endocrinology and haematology) over a 5-year duration compared to the proportion of ISRs conducted in all other therapeutic areas (22 other therapeutic areas such as Immunology, Gastroenterology, Neurology, Paediatric/Neonatology and more).

Source: Clinical Research Malaysia

Addressing the Gaps – Plans and Perspectives

In recognising the need to increase the pool of investigators across the public and private sectors in Malaysia, CRM together with the MoH have embarked on several initiatives to create awareness among investigators on the value and importance of clinical research.

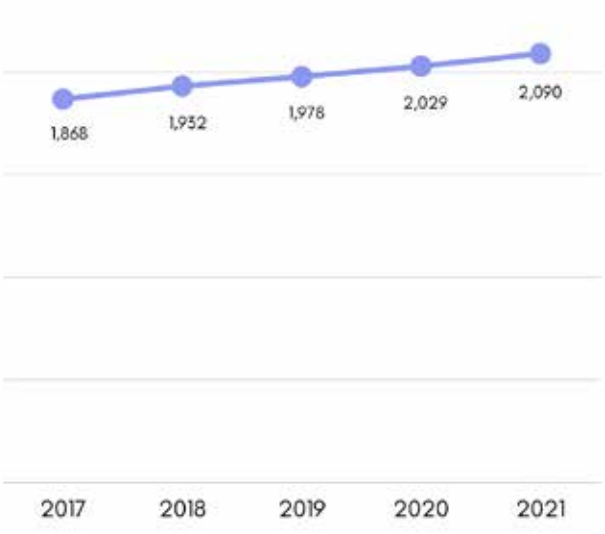

Figure 3. The cumulative growth of new investigators involved in ISR from 2017 to 2021.4

Since 2017, the CRM Sponsored Research Award is given annually to recognise top investigators who achieved excellent recruitment of study subjects, as well as those who have successfully published research articles in high impact peer reviewed journals. To date, a total of 26 awards have been given to top investigators, trial sites, sponsors and CROs in recognition of the contribution to the clinical research industry in Malaysia. Another initiative is through the conduct of a series of seminars and webinars to attract potential and interested specialists to be involved in clinical research. This complimentary programme which started in 2017, includes multiple roadshows in different regions of the country and online webinars that are open to all Malaysian healthcare professionals. To date, over 20 of such roadshows and webinars have been conducted. CRM also publishes biannual bulletins featuring investigators, sharing their experience in clinical research with the objective to motivate up and coming investigators to embark on clinical research. These initiatives carried out indirectly supported the growth of new investigators involved in ISR in the country (Figure 3).

Additionally, to bolster the attractiveness of participating in clinical research as investigators, the Malaysian government continuously strives to improve existing policies that support clinicians. Teaching hospitals within the MoHE allocate sabbatical leave and/or research leave for clinicians to conduct research, participate in clinical research fellowships at global centres of excellence and training attachments at international research institutions. Other than inculcating interest in clinical research, these policies encourage formation of international networking collaborations in clinical research through exposure to high quality research programs and encouraging interactions with other like-minded clinicians.

Meanwhile, the MOH in 2017, had allocated one day a week for clinicians within their facilities to conduct ISR in line with its efforts in increasing the number of clinician researchers in the public sector. CRM also continuously enables and encourages investigators in the MOH to take up clinical research on top of their daily clinical service. CRM supports these clinicians by managing the clinical trial budget and reviewing clinical trial agreements on behalf of the investigators.11 Additionally, CRM also recruits and trains Study Coordinators to be GCP certified, proficient in trial site related duties and comply to CRM's standard operating procedures, before placing them at trial sites throughout Malaysia to support the investigators. These financial, legal and human resource support provided by CRM is vital as it allows the investigators to solely focus on the conduct and delivery of clinical trials, and manage their time between clinical service and clinical research activities.

The growth of the Malaysian clinical trial ecosystem should also consider planning for the future. Hence, as the country gears up for an increase in the number of clinical trials, strategies for career development in clinical research will be needed.

This includes creating new career pathways for the physician-scientist for those interested in focussing on research, and to develop and train support staff with accredited courses for research nurses, clinical trial coordinators and data managers. The rationale is to create pools of qualified and quality members of a clinical research team within established and upcoming clinical trials sites to enable and support the principal investigators. With a well-trained team, the potential for investigators to take on more research activities will increase.

Conclusion

With the establishment of CRM and its collaborative efforts with the MoH and other government entities, Malaysia has made great strides in enhancing its presence in the global clinical research scene. The gaps in the quantity of qualified clinical investigators, mainly PIs, are being addressed to ensure a sustainable pool of investigators. These steps include programs and policies to improve the clinical investigators' time resources, training and mentoring more specialists, and creating an attractive clinical research pathway.

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> **Malaysia will need to increase the pool of available clinical investigators to match the demand and interest of sponsors and contract research organisations in conducting trials here**

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A View of Electronic Signature in Clinical Trial Agreements in Malaysia

Article published in Applied Clinical Trials Online

By Siti Nur Hafizah Binti Adnan, Nuralis Binti Abd Muis and Nurul Atiqah Binti Abd Rahman

A focus on the position of law for e-signatures, their benefits, and the role of Clinical Research Malaysia in educating the industry on the practicality of e-signature.

We all recognize and know that the classic signature is a handwritten representation of a person's name or title. Its legal nature is to verify a person's identity, and it constitutes proof of consent, contractual intention, and endorsement of the information contained in a document. Given the COVID-19 pandemic, digital technology is vital in today's world, and electronic communication has become necessary. The company and business have strived to advance the technology to cater to the industry's uprising needs, including the Clinical Trial Industry. Electronic signature ("e-signature") is an electronic means that indicates a person adopts the agreement's contents and signifies their agreement by capturing their signature through third-party platform/software i.e., DocuSign, HelloSign and the likes, signing on a digital device, signing a document, and sending a scanned copy through email or pasting manuscript of digitized image of the signature. It is a legally recognized means of reflecting the signer's intent to adhere to the terms and conditions of the document signed. Given the circumstances, people must maintain social distance with many workers working from home, and some Principal Investigators (PI) whose signature is required for a Clinical Trial Agreement (CTA) may experience self-isolation at times, it is past time to accept the practise of e-signature, not only during this pandemic outbreak but in the long run term. It is pertinent to note that with travel restrictions, limited access to printers, etc., businesses and individuals will need to adapt and find alternative document signing. Hence, this article will be focusing on the position of law for e-signatures and their benefits and the role of Clinical Research Malaysia (CRM) in educating the Principal Investigator and Hospital Director industry on the practicality of e-signature.

Position of law on electronic signatures

In Malaysia, e-signatures have been legally recognized under the Electronic Commerce Act 2006 ("ECA") to provide for legal recognition of electronic messages in commercial transactions. The act mentioned that any contract should not be denied legal effect, validity, or enforceability because an electronic message is used in its formation.

However, for the e-signatures to be recognized under ECA, an electronic signature must (a) be attached to or logically associated with the electronic message; (b) adequately identify the signer and adequately indicate the signer's approval of the information to which the signature relates, and (c) be as reliable as is appropriate for the purpose and circumstances in which it is required.1 In other words, the usage of e-signatures in the CTA has legal effect enforceable and admissible in court, provided that the legal requirements stipulated in the ECA must have complied. Based on the Contract Act 1950 and the applicable law, if the legally competent parties reach an agreement, whether they agree verbally, electronically, or in a physical paper document to the agreement, it is considered valid agreement despite written signature is not given.2 A signature or e-signature is simply an evidentiary procedure to formalize the parties' intention and enter into an Agreement. Therefore, it can be deduced that any contract or agreement in the business or commercial transaction to be specific for a CTA signed by using e-signatures shall be of the same legal effect, validity, or enforceability as a written executed signature.

Advantages and practicality of electronic signature

There are some advantages of using e-signatures in CTAs. Firstly, using e-signatures in CTA will reduce the time taken for the agreement to be executed. Usually, the parties involved in the CTA will be more than two parties: the sponsor/CRO, PI, and institution. When there are many parties to the CTA, it will take a longer time for the CTA to be couriered from one party to another party for execution. When we can reduce the time taken for the CTA to be executed, it will give another advantage that eventually improves the study start-up timeline to commence a clinical trial. Among the top cause of delays in a clinical trial, is the start-up timeline is due to CTA negotiation and finalization. Implementing e-signatures in the execution of CTA will improve the study start-up timeline in a clinical trial. Besides that, e-signatures also bring the advantage in the business transaction since it is cost -effective. It will reduce the cost of printing and courier delivery service for the execution of CTA. Apart from that, e-signature has a higher level of security, mainly when an e-signature platform is used, as e-signature platforms have encryption software that helps verify the signatory's identity, captured with time stamp, and thus increased the evidential weight to the e-signature process. Less dispute will arise concerning the authenticity of the signatures.

Parties may find fewer documents error if an e-signature is implemented, exceptionally when more than two signatories and more than one CTA are executed for one study. Some parties may inadvertently omit to sign some parts of the document, and the same will have to courier back to them to re-sign. Lastly, using e-signatures in CTA can reduce the physical contact between the staff, such as PI and study coordinator associated with wet-ink signatures, especially during this pandemic outbreak. In summary, there are many advantages of using e-signatures in CTA: time and cost saving, improving the study start-up timeline in a clinical trial, higher level of security, less documents error, and reduced physical contact during this pandemic.

CRM's role

Clinical Research Malaysia (CRM) plays a vital role in expediting the negotiation of a CTA and CRM fully supports and encourages the use of e-signature in CTA and other legal documentations considering its benefit, especially during this pandemic era. The company's practice is to allow and utilize e-signatures whenever applicable in CTA, even before this pandemic. In our effort to create awareness on e-signature, CRM has initiated a discussion with theLegal Adviser of the Ministry of Health ("MOH") to confirm that this arrangement of using e-signature in CTA is in line with the applicable law and regulations. Further, CRM also has created awareness to disseminate the information on e-signature. The information includes the law of using e-signature in CTA and inculcating the benefit of using e-signature in CTA to all the staff, the PI, Hospital Director, Clinical Research Center, and other parties involved in clinical trials via several programs. such as Nurturing New Talent and Investigator Dialogue. By conducting such a program this awareness, CRM hopes that more and more parties are keen to use e-signature in CTA and acknowledged the benefit of utilizing e-signature in CTA.

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> **"Digital technology is vital in today's world and electronic communication has become necessary"**

> **"A signature or e-signature is simply an evidentiary procedure to formalize the parties' intention and enter into and Agreement"**

> **"CRM hopes that more and more parties are keen to use e-signature in CTA and acknowledged the benefit of utilizing e-signature in CTA"**

CRM IN PHOTOS

Annual Report & P1RP Report launch

21 Mar

Meeting with InterVenn

21 Apr

Meeting with Dr Nubli Mustapa from AstraZeneca Cambridge, UK

9 May

Clinical Trials Day Celebration

19 May

Meeting with biotech companies, STALICLA and BeiGene together with YBMK in Geneva, Switzerland

27 May

I AM AWARE Roadshow

31 May – 1 June

Visit by Dr Terada Mistumi, NCC Japan

15 June

Meeting with MiRXES

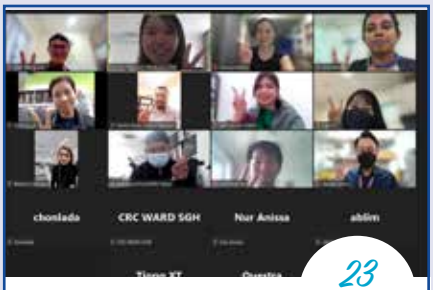
17 June

Meeting with Hays

17 June

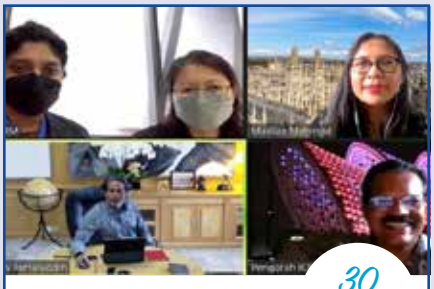
Meeting with Dr Freya Rasschaert and Tan EeLaine from Janssen

21 June



GCP Refresher Workshop

23 Jun



Meeting with Prof Dr Masliza Mahmod, alongside MOH and ICR

30 June

www.clinicalresearch.my

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