BY CLINICAL RESEARCH MALAYSIA

CRM BULLETIN

OF CLINICAL RESEARCH AND THERAPY

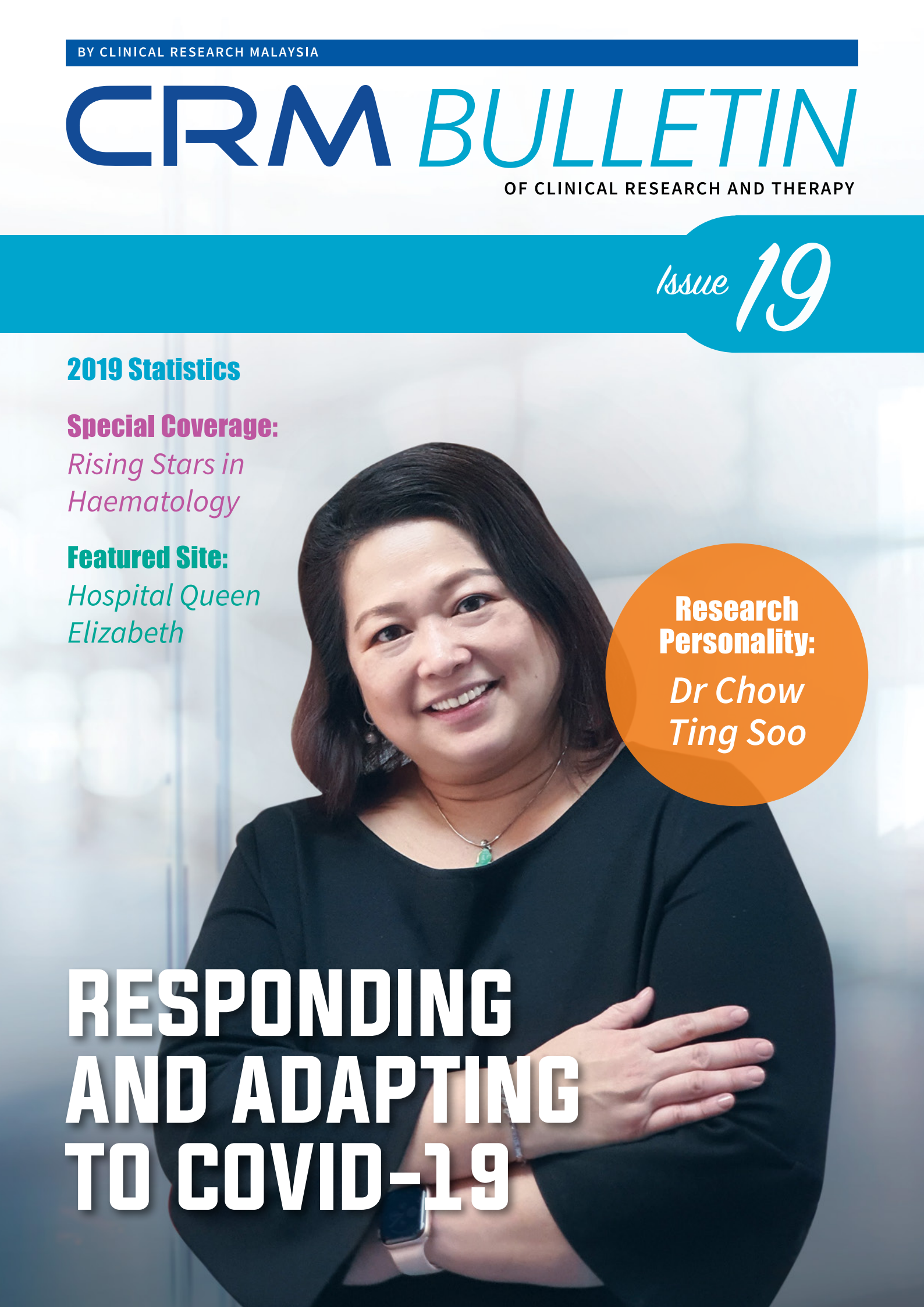
Issue 19

2019 Statistics

Special Coverage:
Rising Stars in Haematology

Featured Site:
Hospital Queen Elizabeth

Research Personality:
Dr Chow Ting Soo



RESPONDING AND ADAPTING TO COVID-19

About Clinical Research Malaysia

Clinical Research Malaysia (CRM) exists to advance global health solutions for a brighter, more hopeful future for the people by providing speedy and reliable end-to-end clinical research support for quality studies. As these studies unfold, we work together with our partners to create an impetus in delivering better treatment to our end consumers, while at the same time creating high-skilled job opportunities.

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

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

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

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

CRM
CLINICAL RESEARCH MALAYSIA
Your Global Solutions in One Nation

From The CEO's Desk

It has been a challenging start to the year 2020 with the Covid-19 pandemic affecting everyone in all parts of the world. In Malaysia, we have flattened the curve and in making social distancing the new 'normal'. Though the healthcare crisis has been mitigated in our local setting, the socio-economic impact is still evident and is here to stay for a while. This is when the whole clinical research industry would need to step up in ensuring deliverance of speed, reliability, and quality in study conduct, all while exploring new concepts in daily operations, especially in working remotely and virtually. Over the past few months, the operations of Clinical Research Malaysia (CRM) have never stopped despite the enforcement of Movement Control Order (MCO), Conditional MCO and Recovery MCO. We may have minimised our in-presence activities and programs, yet we are still committed in remaining steadfast to delivering CRM's key strategies.

I take this opportunity to highlight the outstanding achievements of our clinical study team in driving more quality clinical trials in Malaysia. In May, we celebrated Clinical Trials Day by taking a semi-virtual approach, recognising the contributions of clinical trial volunteers, investigators, trial sites and sponsors/CROs. We were honoured to have the presentation of the CRM Sponsored Research Awards presented by YB Dato' Seri Dr Adham Baba, Minster of Health Malaysia to our award recipients. With such recognition, we hope it will motivate others to continue their efforts in delivering clinical research that can benefit the nation.

During these unprecedented times, clinical trials in Covid-19 vaccine are especially important with the global race to find a vaccine for the pandemic. The participation of Malaysia in the WHO Solidarity trial speak volumes of our speedy regulatory and ethics review but also on the capability of our investigators and trial sites. The last few weeks have also given clinical trials the limelight and prominence it was due with various inter-ministerial discussion with the Ministry of Science, Technology and Innovation and Ministry of Foreign Affairs as well as through Science Diplomacy for potential Covid-19 clinical trials. CRM was also involved in the presentation to the National Science Council chaired by the Prime Minister where we were able to share the capabilities, opportunities, and challenges in clinical trials Post Covid-19.

Finally, I wish all of you safe and to continuously adhere to the standard operating procedures of the Ministry of Health to break the chain of Covid-19 infection.

Dr. Akhmal Yusof
CEO, Clinical Research Malaysia

CONTENTS

IN THE NEWS

Meeting with SunMed and NPRA team

PETALING JAYA, 15 January 2020 – SunMed is developing its early phase clinical research capabilities and CRM looks forward to another accredited Phase I unit for First-in-Human studies in a private sector in the very near future. The meeting was attended by Mr Lau Beng Long (Managing Director, Sunway Group Healthcare Services), Dr Joseph Cheriyan (Clinical Pharmacologist at the University of Cambridge), Professor Ian Wilkinson (Director of Cambridge Clinical Trials Unit), Dato' Dr. Goh Pik Pin and the NPRA team, headed by Datin Dr. Faridah.

Meeting with the Indonesian Ministry of Health and NIH Delegates

SETIA ALAM, 21 January 2020 – A delegation from the Indonesian Ministry of Health and the National Institute of Health Research and Development (NIHRD) visited CRM and the NIH (National Institutes of Health) at Setia Alam. The delegation was led by Dr. Agus Hadian Rahim, the Secretary of the Directorate General of Health Services and Dr. Irmansyah, Director of Centre for Research and Development of Health Resources and Services, NIHRD. The Indonesian delegation was keen to better understand the clinical research ecosystem in Malaysia as they step up efforts to emulate Malaysia's success stories in attracting sponsored research.

CRM Study Coordinator's Training

MELAKA, 29 January 2020 – CRM completed a 2-day workshop for study coordinators in conjunction with the annual National Conference. Ms Carrie Koh from Paraxel was invited to share on effective time management and ways to perform 'root cause analysis'. Coordinators were invited to share the issues that matters, and CRM also had the first CRM Mission Possible games where participants were tested on their GCP knowledge, puzzle solving skills, strategy skills and physicals.

6th Global Quality Assurance Conference

SENDAI, 20 February 2020 – CRM was present at the 6th Global Quality Assurance Conference, held at Sendai, Japan. Being a meet on knowledge exchange in GxP, sessions held ranged from AI in pharmaceutical innovation to compliance and quality assurance in emerging practices/ technologies. CRM also presented a poster during this conference on the success of its GCP Refresher program. Joining along the conference faculty was NPRA who shared on Malaysia's regulatory practices.

Asia Pacific Economic Cooperation Meeting

PUTRAJAYA, 21 February 2020 – CRM took part as an exhibitor in the Asia-Pacific Economic Cooperation (APEC) 2020 First Senior Officials' Meeting (SOM1) at Marriot Putrajaya. Malaysia is the host to the APEC Meetings in 2020 with the mission to lead development of the new APEC vision that will guide the forum's work in the next decades.

Meeting with Delegates from National Cancer Center, Japan

KUALA LUMPUR, 24 February 2020 – The visit of Dr Kenichi Nakamura, Dr Yohei Ohtake, and Ms Tomomi Hata from National Cancer Centre Japan to the National Cancer Institute and Hospital Kuala Lumpur was to meet and discuss with principal investigators at the site on potential oncology studies developed by the investigators at the NCC Japan. It was a great session sharing on aspiration with research and collaboration between National Cancer Center Japan and CRM.

Meeting with Bioeconomy Development Corporation

KUALA LUMPUR, 24 February 2020 – A conducive meet with the Chairman and management team of Malaysia Bioeconomy Development Corporation as CRM explore opportunities in partnering for a better growth of local and foreign research companies in the country.

Global First SIV, Global FPFV and Global FPFT

SARAWAK, 26 February 2020 – Dr. Voon Pei Jye and the research team at Sarawak General Hospital recorded a significant milestone in achieving Global First Site Initiation Visit (SIV), Global First Patient First Visit (FPFV) and Global First Patient First Treatment (FPFT) for the INC280I12201 study, a trial by Novartis.

GCP Refresher Workshop

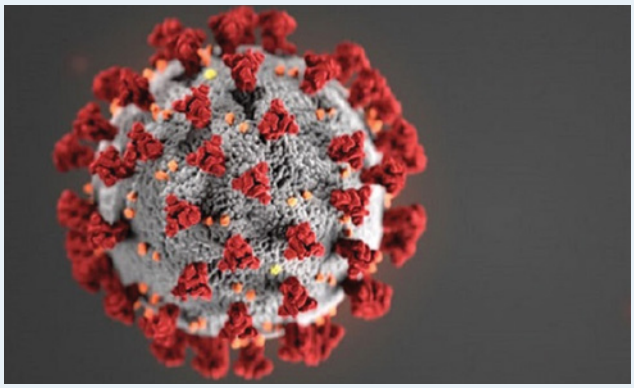
KANGAR, 12 March 2020 – CRM's first GCP refresher workshop for year 2020 was successfully conducted at Hospital Tuanku Fauziah, Perlis. This course is a customised training designed by CRM for investigators/ clinicians who has previously completed GCP training that is approved by National Committee for Clinical Research (NCCR) and/or anyone who with GCP certified.

Global First Patient-in at HRPZ II

KOTA BAHRU, KELANTAN, 20 March 2020 – Dr. Amelia Alias and the research team at Hospital Raja Perempuan Zainab II recorded a significant milestone in achieving first-patient-in globally for the DU176b-D-U312 study, a paediatric trial managed by IQVIA.

SOLIDARITY Trial in Malaysia

MALAYSIA, April 2020 – The global SOLIDARITY trial was initiated at 9 sites in Malaysia and is WHO's effort in testing possible treatments for COVID-19. Over 70 countries will be contributing to this international megatrial that is aimed to produce strong evidence needed in determining the safety and effectiveness of potential treatments. On 23 April 2020, the first randomized Malaysian patient was enrolled in Hospital Sungai Buloh for SOLIDARITY study.



4 Hospitals in Malaysia to Trial Rheumatoid Arthritis Drug in Covid-19 Treatment

MALAYSIA, 11 April 2020 – UMMC, Sungai Buloh Hospital, Kuala Lumpur Hospital, and Hospital Tuanku Jaafar, Seremban to conduct trial on arthritis drug treatment for severe Covid-19 cases. This trial will compare the effectiveness of intravenous tocilizumab (used to treat rheumatoid arthritis) versus high-dose corticosteroids (drugs that lower inflammation in the body) in approximately 300 patients who develop severe forms of Covid-19.

Top Recruiter in Asia Pacific Region

KEDAH, 12 June 2020 – Dr. Eason Chang and the research team at Sultan Abdul Halim recorded a significant milestone in being recognized as 'Top Recruiter' in Malaysia and Asia Pacific region for VALOR-CKD study.

RESEARCH PERSONALITY

Dr Chow Ting Soo

Consultant Infectious Disease Physician, Hospital Pulau Pinang

State Coordinator for Infection Prevention and Control

ABOUT DR CHOW TING SOO

Dr Chow Ting Soo is the Infectious Disease Consultant and Head of Infectious Disease Unit at Hospital Pulau Pinang from 2006 till 2017. She is currently being appointed as Penang State Infection Prevention and Control Coordinator and Hospital Pulau Pinang Infection Control Officer since Oct 2016 and a visiting infectious disease consultant at Gleneagles Hospital, Pulau Pinang. Dr Chow Ting Soo completed her medical degree at University Science of Malaysia in 1996, her MRCP Royal College of Physicians (Edin) in 2000 and her fellowship in infectious diseases in 2006.

Dr Chow Ting Soo is the principal investigator for numerous studies including the WHO (World Health Organization) Solidarity Trial for COVID-19 and D2EFT trail for HIV patients. She is the President for the Malaysian Society of HIV Medicine (MASHM). Dr Chow Ting Soo has published countless clinical papers and posters on infectious diseases and antimicrobial therapy.

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

I was first involved in the trial of Atazanavir for treatment experienced HIV patients in HKL (Hospital Kuala Lumpur) 2003. That exposure gave me a new experience and after completion of fellowship training, I was given the opportunity to be involved as site primary investigator for tigecycline in complicated intrabdominal infection, complicated urinary tract infection and ventilated associated pneumonia. That was my first trial where I was being appointed as primary investigator and I found it challenging, interesting and exciting as well. There were a lot of learning opportunities and that set the platform for my interest to be involved as a researcher and investigator.

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

To handle clinical trials, one has to be thorough in assessment, obsess in completeness of data documentation, accurately recording all process and importance of integrity in managing crisis. This has trained me to become a more thorough clinician and very meticulous in managing case daily.

“To handle clinical trials, one has to be thorough in assessment, obsess in completeness of data documentation, accurately recording all process and importance of integrity in managing crisis.”

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

There are many challenges faced during clinical trial, starting from online training or multiple systems, e CRF systems, GCP courses, protocol training and it all requires spending plenty of time to complete those trainings. In order to complete, one must be organized, and time arrangement need to be done.

Besides, recruitment of participants needs training and the skill of communication must be great and clear. In the process of data collection and procedure to deal with IP, all must be thorough and complete and one single mistake will create major catastrophe outcome to the study. Therefore, when doing clinical trials, protected time must be given to the investigators and full concentration must be applied in dealing with study.

What is your motivation behind conducting clinical trials?

In trials, we get to be involved in answering uncertainties by doing randomised blinded trial, and we get to prove whether a treatment is useful or not. This will give a change in treatment guidelines and ensure evidence-based medicine is practiced.

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

Integrity.

Data cannot be forged or corrected to suit investigator or sponsors in order to produce high quality evidence-based medicine.

"Integrity.

Data cannot be forged or corrected to suit investigator or sponsors in order to produce high quality evidence-based medicine."

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

I wish to see Malaysia as part of global international trials as we are capable to have that in Malaysia. Some HIV trials did not arrive in Malaysia in which I felt we are ready to be involved as part of international research program.

What changes would you like to see being made by the policy makers to create a more conducive ecosystem for the conduct of clinical trials in Malaysia?

To give protected time for investigators and also to support with grant for research especially in the field of infectious diseases which comprise of emerging and re merging infectious agents like Dengue, Zika, Covid-19 etc.

For International trials which do not involve local CRA or CRO, we should have a policy to make it easier for local facility to be able to accept international institute-initiated trials with less red tape.

2019 STATISTICS

Interventional trials accounted for the largest proportion of trials in Malaysia in 2019, with 66 trials (66%) involving new investigational products, 26 (26%) bioequivalence studies and 7 (7%) medical device trials (Figure 1). New investigational products comprise of drugs, biologics, biosimilars or supplements.

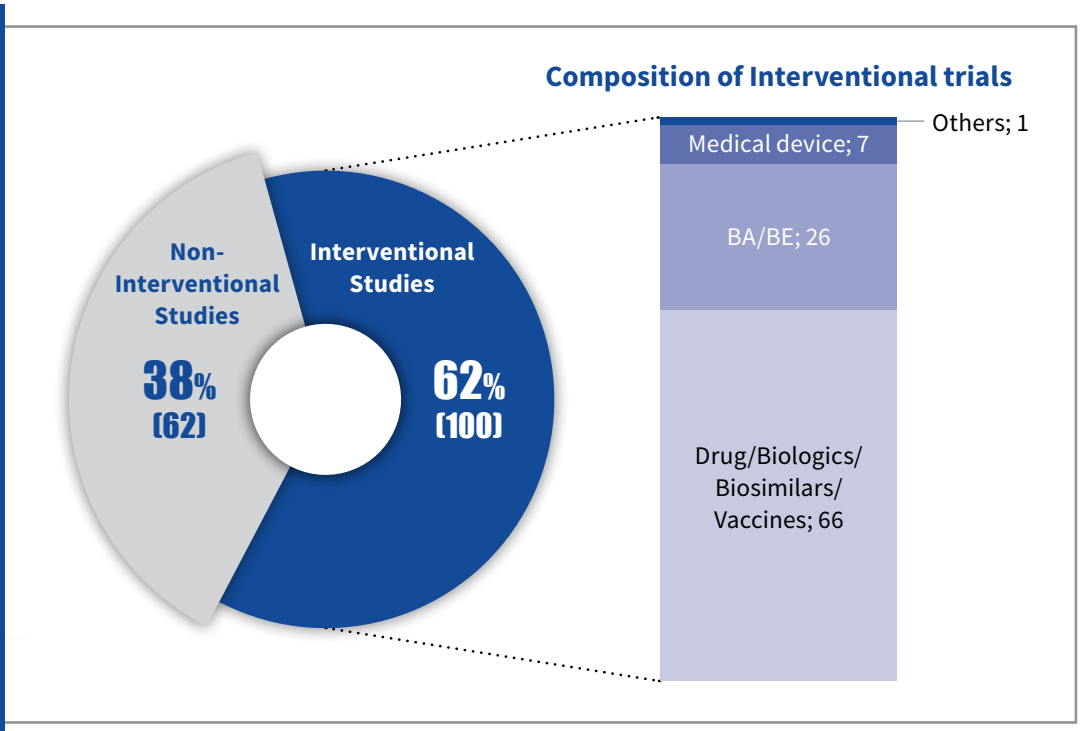


Figure 1: Breakdown of studies according to Intervention, 2019

Out of all interventional trials, Phase III trials records the highest number of trials followed by, bioavailability/ bioequivalence (BA/ BE) studies, Phase II, Phase IV and Phase I (Figure 2).

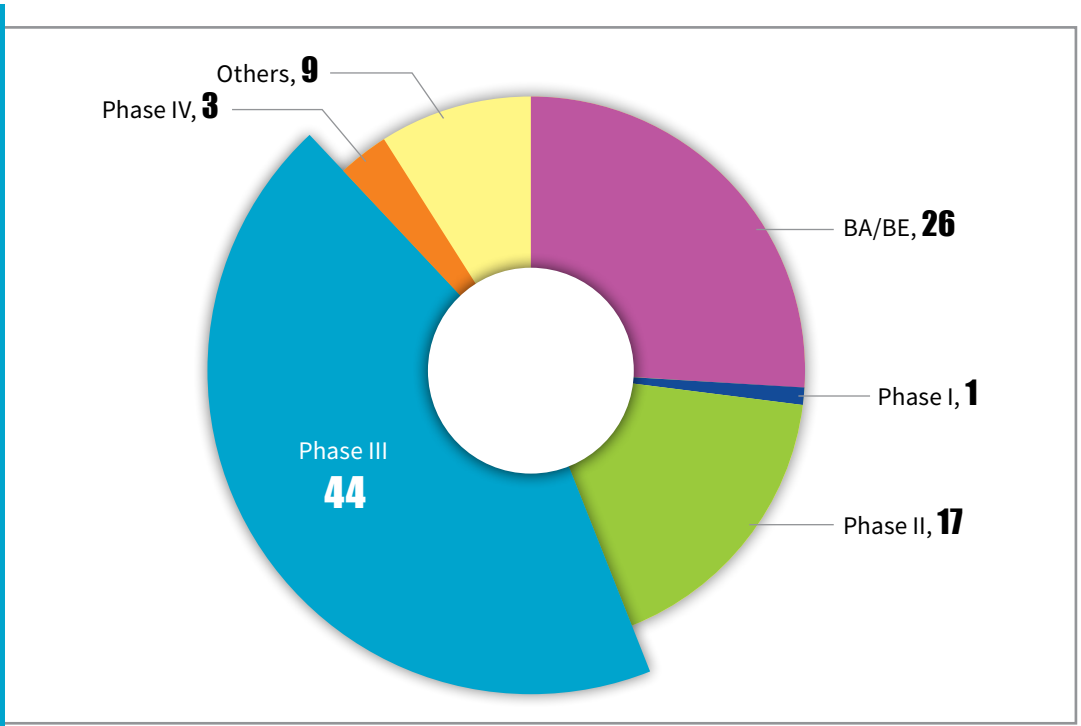


Figure 2: Classification of Interventional studies in Malaysia, 2019

Disease patterns in Malaysia are almost like those in developed countries. Malaysian patients have similar unmet medical needs that these countries have. Cancer and cardiovascular disease are the major cause of mortality and morbidity in Malaysia. The high incidence of these noncommunicable diseases provides a large patient pool for clinical trials in these therapeutic areas. In 2019, oncology trials accounted for the highest number of trials followed by haematology and cardiology trials (Figure 3).

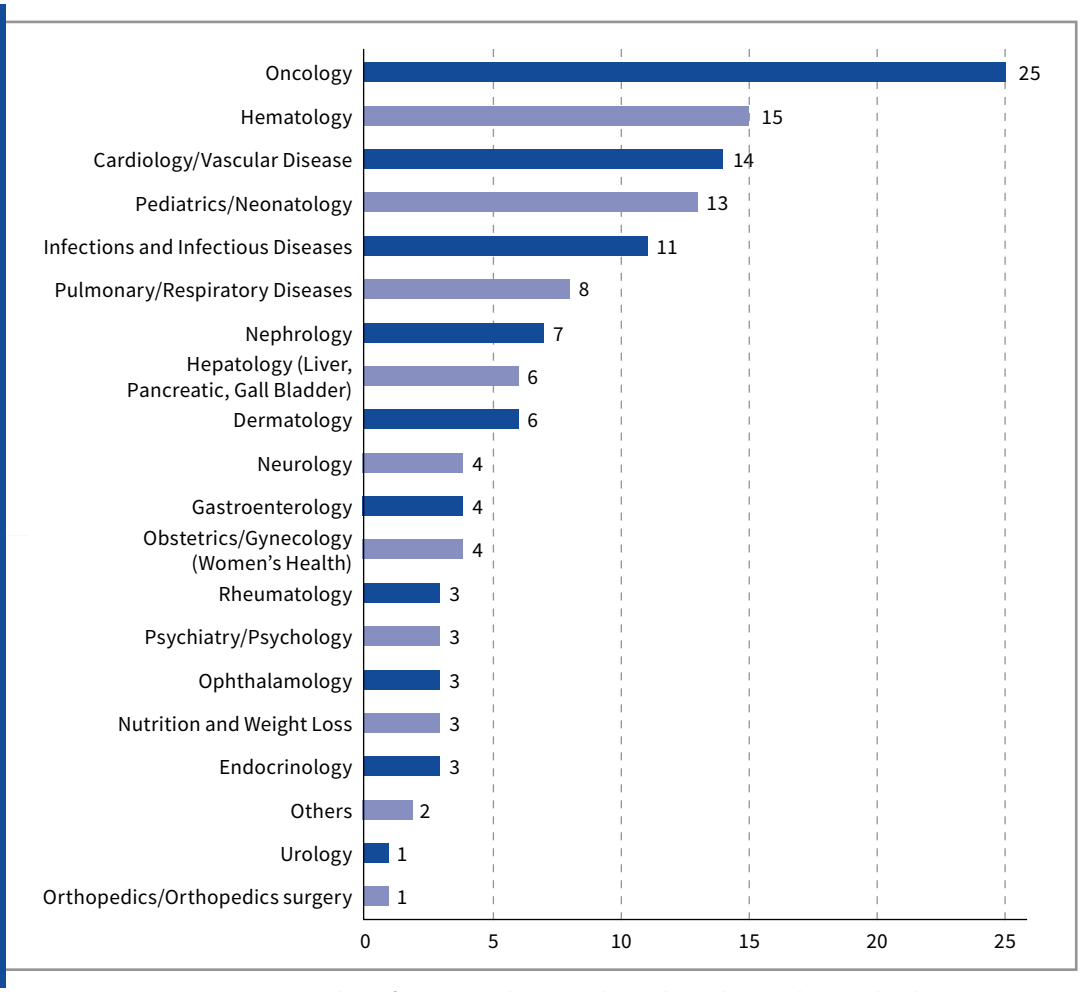


Figure 3: Number of Sponsored Research conducted according to the therapeutic area in Malaysia, 2019

Meanwhile, University Malaya Medical Centre was recorded to have the highest number of trials in Malaysia for 2019 followed by Hospital Pulau Pinang, Hospital Ampang and Sarawak General Hospital (Figure 4). CRM has been involved in the trials at most of the Ministry of Health sites, whereby it has assisted investigators in the review of the study budget and clinical trial agreement, as well as in providing study coordinators.

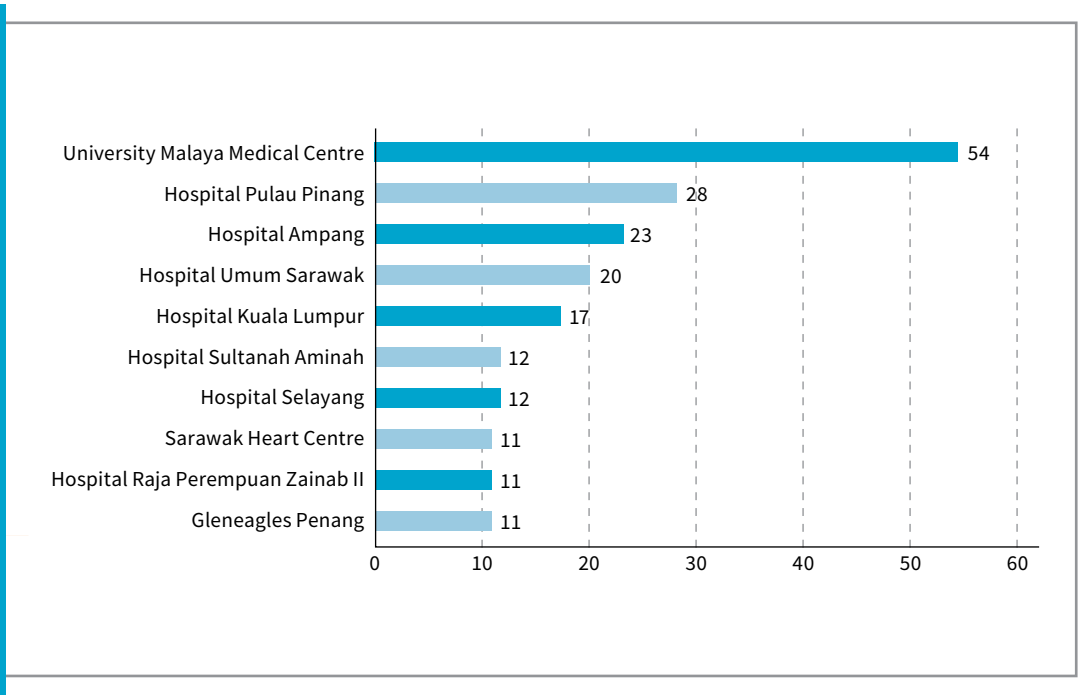


Figure 4: Top sites awarded with sponsored research on Malaysia, 2019

SPECIAL COVERAGE

Rising Stars in Haematology

Dr. Yap Yee Yee
Clinical Haematologist

Department of Haematology
Ampang Hospital
Ministry of Health

I was first involved in clinical research when I joined haematology subspecialty via the leadership of our astute consultant haematologists. Clinical trial has provided opportunity to patients to access to the novel agents in both the haematology-oncology trials and the haemostasis thrombosis trials. Overseas, clinical trial is actually part of the management for patients who have exhausted the standard of care treatments. I would like to do investigator-initiated trial which can answer a lot of clinical questions. I had experienced some translational research in Perth in 2017 which was more challenging as it required numerous hands-on and benchwork. I would definitely recommend my peers to join clinical research. It is the gateway to evidence-based medicine, plus the data of novel agent in Asian population is always lacking. This will definitely help us to understand our local patients better in terms of dosage, response and toxicity of the novel agents as well as whether in future worth incorporating into our standard of care treatment.

Dr Norasmidar binti Abdul Aziz
Haematologist

Hospital Sultanah Bahiyah

I have been involved in many haematology studies, mainly on thalassaemia, paroxysmal nocturnal haemoglobinuria and myeloma. I hope to be involved in more clinical trial on other haematology disease, for example thalassaemia and haemophilia in the future. In my early years as a Medical Officer, I was persuaded by my Head of Department, Dato Dr. Muhammad Radzi to entail in epidemiology research. I gradually found this area to be interesting and inspiring in nature. When I was undertaking my subspecialty training at Hospital Pulau Pinang, my supervisor encouraged me to pursue my studies related to clinical trials. I really wish that one day I will be given more responsibility to lead clinical trial. I am amazed on the procedural and organisational arrangements related to clinical trials and the indispensable impact to subjects involved. Every detailed information is being documented through an appropriate procedure. Sometimes, its time consuming in delineating and verifying the procedures. However, I realised that the meticulous procedures on clinical trial improves the patient's response to treatment. Undeniably, I gradually follow the best practice provided even after the trials. I believe by getting involve in clinical trial, doctors can be more responsive and effective clinician for the betterment of the patients. I would certainly recommend my peers to pursue on clinical research. I feel doctors should participate because it assists them to practice better clinical medicine. When undertaking clinical trials, it reflects a huge chance for a better treatment and clinical practices to the respective patients.

Dr. Azizan Bin Sharif
Clinical Haematologist

Hospital Sultanah Aminah
Johor Bahru

I was encouraged by my Head of Department at that time. She made sure all the senior Medical Officers sat for the Good Clinical Practice (GCP) course & exam. The GCP course was my 1st exposure to the world of clinical trial. Soon after, HSAJB was chosen as one of the sites for an observational stroke trial – Strokop Asia. I was roped in as one of the Co-I for the trial. By conducting clinical trials, I have gain exposure to new treatment options and modalities into my day to day practice. Often times, the best clinical practice for any given disease is unclear especially so for rare diseases. Clinical trials are the best avenue to answer this question. By enrolling into clinical trials, patients gain access to state-of-the-art treatment options which they would have never been able to obtain otherwise.

Dr. Veena A/P Selvaratnam
Haematologist
MBBS(UM) MRCP (UK)
FRCPath (UK)

Hospital Ampang

I initially chose to be a doctor as it was my parents wish to follow their footsteps. Haematology is a very interesting field of Medicine whereby the clinical and the laboratory aspect plays an equally important role in patient management. In this field, clinician not only treat the patient but also plays the role of a pathologist in making diagnosis and monitoring of disease progression. The significant bond between the clinical and pathological correlation in this field is truly crucial and being able to play both roles in patient management makes this field truly unique, unlike any other fields of medicine. Furthermore, I was fortunate to work under extremely passionate Haematologists as a junior doctor who inspired me to embark on a carrier in this field. The late Dr Visalachy Purushotaman, Dato Dr Chang KM and Dr Jameela Sathar are my main mentors who have continued to encourage me in my carrier progression in this field. Clinical trials provide new treatment options/approach for patients. This gives opportunities for us as clinicians to explore new treatment strategies as well as gives patients a chance for a potential cure/better quality of life. Clinical trial also widens the knowledge and allows clinicians to think outside the box when treating patients; especially when dealing with complex cases. It is very satisfying to see patients to respond well to these new modalities of therapy. Some of these patients occasionally have no other definitive options for treatment and seeing them improve with these new treatments offered is truly rewarding. It gives us a sense of fulfilment that no words can describe. That itself is a great motivation. Though it's time consuming as we have to do extra paperwork and see patients more often; it is all worth it.

"The significant bond between the clinical and pathological correlation in this field is truly crucial and being able to play both roles in patient management makes this field truly unique"

CRM INFOGRAPHICS

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

http://clinicalresearch.my/investigator/investigator-information-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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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

FEATURED SITE

Hospital Queen Elizabeth

Hospital Queen Elizabeth is the main hospital in Sabah built in 1957 in Jesselton as soon as World War II ended. The official opening was done on 15 September 1957 by The Right Honourable The Countess of Perth. The building was initially built with wood. In the early days, the hospital consisted of only 1 block which is now known as "Bangunan Hospital Lama". The hospital started with 208 beds. Now, Hospital Queen Elizabeth is the largest hospital in Sabah. It is the referral center for 32 hospitals with 670 operational beds. Hospital Queen Elizabeth contains of a few specialty units, including Burn Unit and Paediatric Intensive Care Unit. Hospital Queen Elizabeth is accredited with MSQH and MS ISO 9001:2015. They have served over the population of 783, 000 including Putatan district, Penampang district and Kota Kinabalu.

MAIN DEPARTMENT (7)

- General Medicine
- General Surgery
- Orthopaedic
- Otorhinolaryngology
- Ophthalmology
- Anesthesiology
- Psychiatry

SUB-SPECIALTY

- Endocrinology
- Gastroenterology
- Haematology
- Infectious Disease
- Nephrology
- Neurology
- Rheumatology
- Respiratory Medicine
- Geriatrics
- Plastic & Reconstructive
- Neurosurgery
- Urology
- Palliative Care
- Sports Medicine
- Rehabilitation
- Paediatric Dental Surgery
- Dental Surgery
- Hepatobiliary Surgery
- Breast & Endocrine Surgery
- Medical Transfusion Specialist
- Ophthalmology VR
- Paediatric Ophthalmology
- Vascular Surgery
- Dermatology
- Wound & Stroma Care

670 Operational Beds

594 Doctors

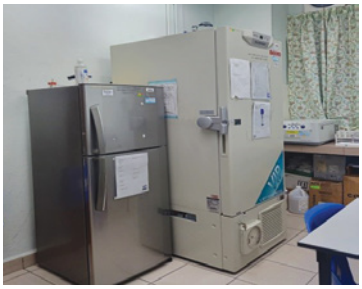
1572 Nurses

3664 Staffs

OPERATIONS

Clinical Research Centre (CRC) Hospital Queen Elizabeth

The CRC in Hospital Queen Elizabeth started operating in 2008 with its premise temporarily located in the Continuous Ambulatory Peritoneal Dialysis Unit (CAPD Unit) in Queen Elizabeth Hospital. In March 2010, it officially moved to its own premise, a modest colonial bungalow converted into office, within the Queen Elizabeth Hospital compound. The current head of CRC is Dr Nagarajan A/L Nagalingam.

Clinical Research Facilities

Workstation

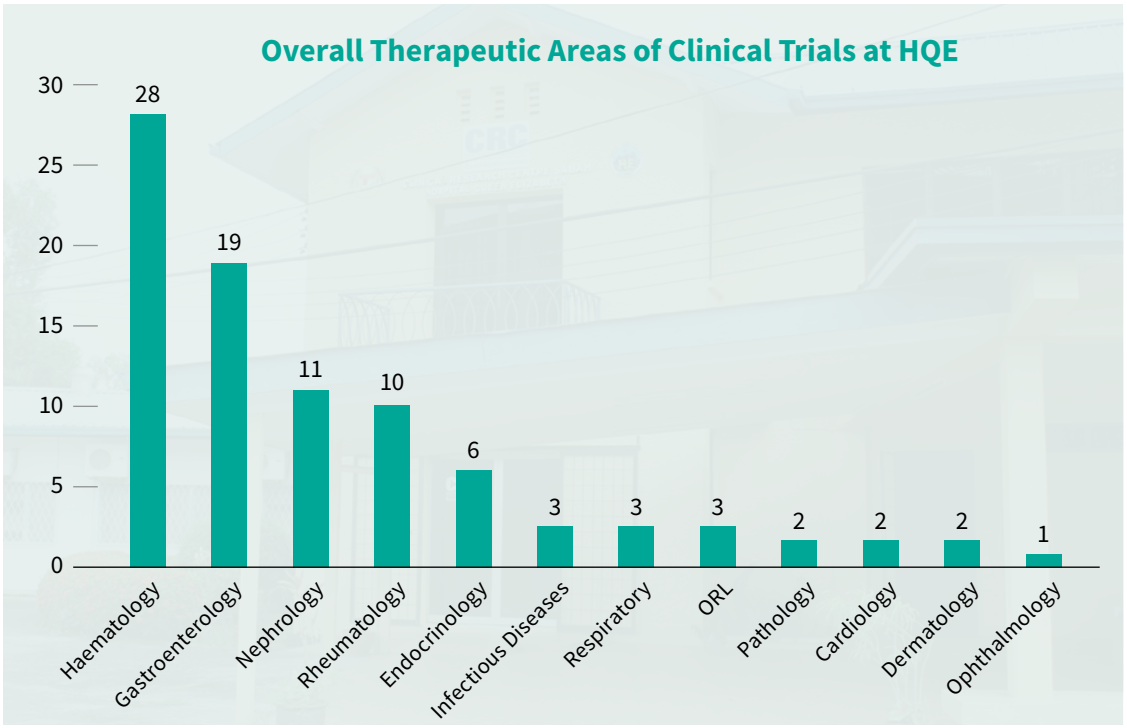
Mini Laboratory
- Freezer (-86 degrees)
- Centrifuge
- Incubator

IP Storage
- Pharmaceutical Refrigerator
- IP room (Room temperature)
- Thermoguard Monitoring System

TRIAL EXPERIENCES

89 ISR Clinical Trials

426 Feasibility received by site



CLINICAL TRIALS DAY 2020

A Tribute to Our Heroes on International Clinical Trials Day

KUALA LUMPUR, 20 May 2020 – The clinical research community in Malaysia celebrated Clinical Trials Day together with the rest of the world. This year, the celebration was done at a smaller scale to conform to social distancing and to avoid large gatherings amid the current COVID-19 outbreak. International Clinical Trials Day is celebrated around the world on May 20 every year to recognize the people who conduct clinical trials as well as the volunteers and patients who participate in it.

Clinical Trials Day has always been part of Clinical Research Malaysia's (CRM) ongoing effort in creating awareness among the general public, patients as well as healthcare professionals that contribute to the development of better innovative treatments in the medical field.

To acknowledge the contribution of medical professionals in sponsored clinical research, a small presentation ceremony was held at the Ministry of Health complex in Putrajaya. The Minister of Health, YB Dato' Sri Dr. Adham bin Baba, who is also the Chairman of CRM's Board of Directors, presented the CRM Sponsored Research Award to five recipients in recognition of their significant contribution in clinical research, as well as to spur and encourage more of such efforts.

YB Dato' Sri Dr. Adham stressed the importance of clinical trials to assess the safety and effectiveness of treatments. Malaysia has been a significant contributor in various drug and medical device clinical trials and the latest being the country's involvement in the WHO Solidarity Trial to test several drugs in treating COVID-19. "Participation in clinical trials provides our patients with treatment options, especially those who have not responded well to the current standard of care or available treatment," said Dr. Adham.

Clinical Trials Day 2020

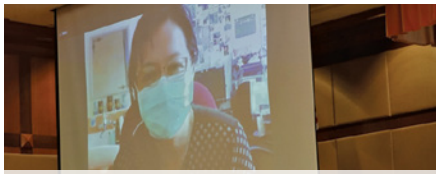
CRM SPONSORED RESEARCH AWARDS 2020

The CRM Sponsored Research Awards has been a significant part of the nation's Clinical Trials Day program organized by CRM annually since 2017. Through this awards presentation, CRM tributes outstanding accomplishments and contribution by the industry, trial sites and investigators in elevating sponsored research in Malaysia. The following are the recipients of CRM Sponsored Research Awards 2020.

TOP RECRUITER

DR VOON PEI JYE, SARAWAK GENERAL HOSPITAL

— for achieving significant patient recruitment in studies initiated in 2019. Out of the studies initiated in 2019, Dr Voon had 6 studies which achieved 1st patient enrollment within 3 months from study activation. He has also achieved the patient recruitment target in 3 of these studies.



INVESTIGATOR OF THE YEAR

DR LILY WONG LEE LEE, HOSPITAL QUEEN ELIZABETH

— for being Principal Investigator to the highest number of new sponsored research in 2019. Dr Lily Wong is the Principal Investigator in 9 out of the 15 new hematology trials which was awarded in Malaysia in year 2019. She also co-authored in a global sponsored study finding which was published in high impact Blood journal in 2019.

CLINICAL TRIAL SITE OF THE YEAR

HOSPITAL SULTAN ISMAIL

— for demonstrating significant growth in the number of studies awarded in 2019. This clinical trial site had 8 studies which was initiated in 2019 compared to only 2 studies the year before, making it one of the top trial sites for oncology and dermatology studies in the country.

SPONSOR OF THE YEAR

MERCK SHARP & DOHME (MALAYSIA) SDN BHD

— for contributing the highest number of new trials in 2019. MSD also brought in the highest study value in contract for that year, which contributed a total of 47.6% of the total study value recorded.

CRO OF THE YEAR

IQVIA RDS MALAYSIA SDN BHD

— for contributing the highest number of new clinical trials in 2019 as a CRO. In addition, not only IQVIA did achieved the highest number of clinical trial sites initiated that year, these trial sites showed remarkable achievement in terms of recruitment achievement.

KNOWING CLINICAL TRIALS 101

Gearing Towards Remote Monitoring Visit

By Soon Wen Xian, a medical graduate from Volgograd State Medical University, a Clinical Research Associate at an international pharmaceutical organization based in Singapore.

The Coronavirus outbreak changed the way the world works. Can the clinical trial industry evolve fast enough to cope with the need to adapt to the new normal and challenges associated to it?

Clinical trial involves many processes and one of it is monitoring visit. Monitoring visit requires a Clinical Research Associate (CRA) to travel to the trial site to audit the data gathered from the sites to ensure integrity of the trial data. It is common for pharmaceutical companies to outsource this process to contract research organizations (CROs). In the last five years, sponsors and CROs are moving towards risk-based monitoring, a clinical trial monitoring technique that fulfils regulatory requirements but moves away from 100% source data verification of patient data.

The main purpose of the idea is to reduce the site visit frequency but at the same time, to ensure integrity and quality of collected patient data, without which the trial data may be compromised.

When risk-based monitoring was attempted to be implemented at the site, one of the challenges encountered was that CRAs were unable to review the source document virtually.

The coronavirus pandemic has somehow speed up the need for risk-based monitoring. All monitoring visits were put on hold while the trial sites coped with the influx of COVID-19 patients. CRA's were only able to perform off-site monitoring through phone/video call with the study coordinator/research team at the site. However, scanning of documents by the study coordinator and giving access of electronic medical record (EMR) to the CRA may not work for both parties. The main challenge is data privacy/data protection laws as access to the EMR system or through video call may result in leakage of patients' data. Thus, not all monitoring activities can be conducted over the internet which results in the shortfall of the risk-based monitoring method.

There are a few challenges that CROs and trial sites must overcome. Remote access to medical record is the most important part for SDV. Trial sites should readily employ electronic medical record (EMR) system that allows CRAs to access the system.

This access will not only benefit the clinical research process but allows doctors in different healthcare facilities and geographically diverse regions to discuss case studies.

The preparation made for remote monitoring and on-site monitoring visit are very different for the study coordinators (SC). For on-site monitoring visit, SC will have to ensure that all study related documents are prepared and provided to the CRA to review. In the after process, the CRA will spend about half an hour to summarise the monitoring visit and make a trip to related departments including the IP and sample storage room. In the event where remote monitoring visit is to take place, the SC would have to provide some documents in soft copy format before the visit such as the delegation log, IP temperature log etc. During remote monitoring, SC will have to sit through the video call for at least an our as the CRA goes through the medical record for all recruited patients as well as review the site file. This may introduce administrative burden to SCs and compliance risks. Also, to ensure the process goes smoothly, it is imperative for a continuous and strong internet connectivity at the trial site.

On CROs part, remote monitoring visit is a long process which may take up 1 to 2 hours of video call. Information that should be conveyed to SC include the process of the monitoring visit and the documents that are expected to be provided prior and during the video call. CRA's should also review the Electronic Data Capture and resolve any query before the engagement with the study coordinator to reduce remote monitoring visit time. During the video call, focus should be on issues or findings that are unable to be resolved through email. This may include source data verification (SDV), recruitment challenges or discussion on required training. The main challenge for remote monitoring visit is the SDV process and CROs should not expect that CRAs will be provided full access to the system. Full SDV or random screening of subject data for 100% SDV can be completed during the on-site MV. With less time spent on travelling, CRAs will be able to complete more than one monitoring visit in a day. Remote monitoring visit may be an efficient way in monitoring clinical trials moving forward. Nevertheless, the challenges need to be ironed out to ensure success and this include having an appropriate monitoring program in place, EMR system, tackling issues related to data privacy and protection, etc.

Conducting Clinical Trials During A Pandemic

By Veeranarasimman A/L Ravendran, CRM Study Coordinator, Hospital Pulau Pinang

Viral disease outbreaks are continuously emerging within the society and causing serious public health issues. It has impacted severely on global health and world economy. Like any other viral disease outbreak the world has seen, COVID-19 is considerably extreme as it causes high infection rate in a short period of time. The outbreak which began in December 2019, was later declared as a pandemic by World Health Organization (WHO) and has spread to all continents globally except Antarctica.

Study management and communication are conducted remotely to address safety concerns of the study participants and site team.

The COVID-19 pandemic has led to substantial changes in health risks and its management, access to health care system, and daily patient – health professional interactions.

The conduct of clinical trials aiming in treating and preventing diseases other than COVID-19 has also been affected, as greatly seen on trial subject recruitment. Challenges arose from difficulties in meeting protocol-specified procedures during the pandemic for e.g., from hospital restriction, travel limitations, safety concern of the trial subjects and site personnel and thus it is recognizable by the regulatory authorities and Ethics Committee that protocol modifications may be required and there may be unavoidable protocol deviations due to COVID-19.

Research sponsors and CROs have been diligently working on modifications of study procedures in response to the pandemic to ensure continuity of trial. Study management and communication are conducted remotely to address safety concerns of the study participants and site team. Sponsors are effectively completing risk/benefit assessments for all trials and to review the need for trial extension in term of its duration, processing critical and essential laboratory testing as well as suspending or slowing down on subject recruitment for trials.

The conduct of clinical trial during a pandemic is highly challenging. These challenges require efficient and robust monitoring from all stakeholders, with active engagement and communication among all. In keeping to the pace of trial operations, every individual involved in a clinical trial is responsible to continue their efforts in assuring the safety of trial subjects, while maintaining compliance to Good Clinical Practice, and minimizing risks to trial integrity.

Ensuring Effective Financial Management in Sponsored Research in Malaysia

Published in Journal for Clinical Studies, Volume 12, Issue 1, 20 February 2020

By Yau Yit Huan (Head of Finance & IT) & Audrey Ooi (Head of Business Development) in Clinical Research Malaysia

The principles of developing, conducting, analysing and subsequently reporting clinical research are widely known.[1-3] However, the success of a clinical trial goes beyond these principles. It also requires a structured, viable and business like management of the whole process, without which trials may fail.[4] A critical part of managing clinical trials is a solid, well thought out clinical trial budget.[5] A successful budget to ensure a good quality clinical trial should not only entail careful detailing of costs that are in line with the trial protocol, but should also include a financial management system that executes this budget in an efficient, timely and transparent manner.

Some issues and challenges in formulating clinical trial budgets could be applicable when managing the finances during conduct of the trials. Examples include how to maintain audit trails and being abreast of billing processes, ensuring all costs have been encountered for, and management of residual monies. Though ultimately the responsibility of the principal investigators, the detailed construction of a clinical trial budget and its management places a huge burden on physicians (or researchers) who have to juggle clinical practice while overseeing the running of multiple clinical trials.

Reducing the Burden of Principal Investigators

Established in 2012, the main objectives of Clinical Research Malaysia (CRM) are to effectively increase the speed, reliability and quality in delivery of outcomes of clinical trials conducted within the country. This is in line with the Malaysian government's vision to enhance the country's placing among other clinical trial hubs as a preferred global destination for clinical research.[6] CRM, therefore, is also equipped to manage the financial aspects of clinical trials and is currently used extensively by principal investigators, investigators, contract research organisations (CRO) and sponsors conducting clinical trials in Ministry of Health facilities.

CRM's financial management services extend throughout the trial process, i.e. from prior to study initiation to its close. Legal services are also included during the initial process to support the management of clinical trial agreements (CTAs), parallel with negotiations and refining of the trial budget. CRM reviews and endorses the study budget for the CTA within seven working days (from the last feedback date received from the relevant party involved in the budget negotiation). CRM takes on full financial and administrative duties that include initial budget negotiation with sponsors/CROs and investigators, keeping track of the trial progress, budget and invoicing, receipt of funds from sponsors/ CROs and payments to various stakeholders involved. CRM also prepares statements of account for the principal investigators on a monthly basis to facilitate better planning of clinical trial activities.

Facilitating Initiation of Clinical Trials

Involvement of the finance team starts just prior to initiation of the clinical trial in collaboration with the legal department, principal investigators, CROs and sponsors. This is crucial, as CROs, sponsors and investigators each bring expertise required for the conduct of specific types of trials, whilst the finance team contributes with their experience working on the financial aspect of clinical trials across the board. The legal team facilitates the process by ensuring that the CTA meets local requirements. The finance team also supports CROs, sponsors and investigators when negotiating and finalising the trial budget with approval from these parties. The timeframe for this process is expedited by a dedicated team handling the details of the negotiations and preparation of the approved final budget for submission, though it is still dependent on response time from CROs, sponsors and investigators.

Financial Management During Trial Conduct

CRM's involvement in the management of the clinical trial budget is to reduce payment time through a standardised financial process by prompt issuing of invoices and providing efficient disbursements of payments. This ensures that the financial management of clinical trials conducted by investigators at their respective clinical trial sites has a proper audit trail and is executed in an efficient and transparent manner.

Prior to the establishment of CRM, all financial transactions to and from government linked facilities were routed via established local medical societies or the clinical research arm of the Ministry of Health (Clinical Research Centre). Between 2012 and March 2015, payments to investigators had to go through a trust account under the purview of the Director of Kuala Lumpur Hospital. Due to red-tape processes, payments could take at least a month.

However, from April 2015, CRM's role expanded to making payments out directly to investigators and study team members (specifically government-employed staff affiliated with Ministry of Health facilities) and similarly reduced the timelines to within two weeks. With the advancement of online banking facilities in Malaysia, these timelines have further reduced. In 2018, the total value of trial budget managed by CRM was RM 39.5 million, compared to 2015 which was only about RM8.3 million, translating to more than four times in the growth of the budget management.

In addition, CRM's responsibilities encompass ensuring there are enough funds available for the smooth running of a clinical trial by keeping track of the budget and communicating with sponsors so that payments are as scheduled in the trial budget and CTA. If, for any undue reasons, receipt of funds from sponsors is delayed, CRM steps in to guarantee timely payments to vendors and study subjects, ensuring that trials are on track. All receipts and disbursements of funds are carefully tracked, and monthly statements of account are sent to the principal investigators for review. All financial processes performed by CRM are also audited by internal and external auditors, which include the National Audit Department and the Ministry of Health. During the close of a trial, CRM provides an added service of negotiating the best price for archiving trial-related documents from third-party vendors. This enables cost savings in a clinical trial budget as well as more efficient conduct during clinical trial study closure.

Conclusion

CRM in essence acts as an account manager with in-house expertise in clinical trial budget management. Its focus is to streamline the processes for all clinical trials conducted in Ministry of Health facilities and involving Ministry of Health staff. CRM facilitates the clinical trial process from the budget negotiation stage, receipt, and disbursement of study funds and lastly, archiving services upon study closure.

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Access to Biological Resource and Benefit Sharing Act 2017(Act 795) Malaysia: Legal Opinion on the Implementation of the Act to the Clinical Trial Industry and its Negative Impacts

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By Nurul Atiqah Abd Rahman (Senior Legal Executive), Siti Nuralis Abd Muis (Legal Executive) & Siti Nur Hafizah Adnan (Legal Executive) at Clinical Research Malaysia's Legal Department

The Act was announced by Natural Resources and Environment Ministry to be implemented in Malaysia in 2017. It was aimed to regulate the use of biological resources, addresses issues of biopiracy and ensures that result benefits from the access of biological resources are shared equitably. Its content is mainly to conserve and reserve the biodiversity ecosystem in Malaysia for instance, conservation of natural resources like plants, animals but also included the access to human genetic resources. Access to human genetic resources will surely impacted the Clinical Trial Industry in Malaysia. As Clinical Research Malaysia is a company owned by the Ministry of Health Malaysia where we act as a one stop center for Clinical Trial Industry ("the Industry") in Malaysia we opined that **the implementation of the Act will have several negative impacts in the Industry** as such our intention in writing this article is to inform the industry and also the relevant parties as to why similar Act should not be implemented to Clinical Trial Industry be it in Malaysia or other countries and how this is actually has been curbed through the initiative taken by Clinical Research Malaysia.

The Act sets out the requirements for access to Biological Resources or Traditional Knowledge associated with Biological Resources for research and development activities[1] whereby the implementation of the Act is to protect the use and access of Biological Resources in Malaysia. Whereas, Clinical Trial is a scientific study that prospectively assigns or conducted on human participants or groups of humans to one or more health-related interventions as a mean to treat, prevent, diagnose or manage various medical condition or diseases[2] and also to evaluate the effects on health outcomes, the inventions may include but are not restricted to drugs (investigational products), devices, surgical procedures, cells and other biological products, radiological procedures, behavioral treatments, preventive care and others[3]. It is human rights that one should have the access to health care. Enforcing the Act to the Clinical Trial Industry would add more steps and more guidelines for a Clinical Trial or Study to be conducted in Malaysia which may lead to the delay in completing the Clinical Trial and may further lead to the depletion of Clinical Trial in future.

Obtaining Permit under this Act

Under the Act, any local or foreign individual or corporation who intends to access Biological Resources or Traditional Knowledge associated with Biological Resources for commercial, or potentially commercial or non-commercial purpose must obtain a permit, violation of this application of permit may cause the relevant party to be penalized. However, a permit may not be required for any research and development activity that is under a public higher education institution, research institution or Government agency within Malaysia, the exchange of Biological Resources between persons within a public higher education, institution, public research institution or Government agency within Malaysia or the access is by any person outside Malaysia or in a private institution within Malaysia from a permit holder who possesses a valid permit to access for the purpose of carrying out or continuing any research for non-commercial purpose.[4] Under the Act, in order to have access to biological resources and to obtain a permit to access biological resources, the accompanying documents required to be submitted along with an application for a permit is the Prior Informed Consent which has to be obtained from Indigenous local community, organization, resource provider or their representative and Benefit Sharing Agreement that has to be entered into with the resource provider who gave access to the Biological Resources or Traditional Knowledge. A Benefit Sharing Agreement under the Act is described as a legally binding contract entered between the person who intends to access the resources or traditional knowledge relating thereto with the resource provider and shall be based upon mutual agreed terms and provide a fair and equitable benefit sharing.[5]

Benefits in Protecting Our Natural Resources!!

In our humble opinion, we do agree that the implementation of this Act may bring a lot of benefit in protecting our natural resources but not when it comes to conducting Clinical Trial which is a solution to provide a better healthcare and medicine to Malaysian citizen. The contention on our stand to oppose the application of the Act to the Industry is substantiate on few comprehensive measures currently exist in Malaysia to regulate and control Malaysian Clinical Trial Industry. First, conducting Clinical Trial in Malaysia already have their own guidelines that spells out the procedures in conducting Clinical Trial or Study such as the Good Clinical Practice guidelines. Second, to regulate and oversee the Clinical Trial or Study conduct as well as to approve the application of import license or exemption of the investigational product/drug, the regulatory body/ authority like the National Pharmaceutical Regulatory Agency (NPRA) plays a significant role. Third, the presence of Medical Research and Ethics Committee (MREC) that approves the trial, are sufficient enough as all the protocol, procedures of the Clinical Trial have been examined carefully and thoroughly by the said authority/regulatory body to ensure that it is safe,

ethical and further comply with all the requirements and guidelines in conducting Clinical Trial.[6] Fourth, as patients' consent is the utmost consideration before enrolling them as Clinical Trials subjects, their rights are protected and respected where prior to Clinical Trial is being conducted, informed consent must be obtained from the patients.[7] Legally speaking, the law on contract has evolved as a framework to regulate voluntary exchange transaction. Informed Consent is a voluntary agreement to participate in research. It is not merely a form that is signed but is a process, in which the subject understands the research and its risks. Informed consent is essential before enrolling a participant and ongoing once enrolled. Informed Consent obtained from the patients prior to enrol them as the participating subjects in the Clinical Trial is sufficed to reflect the voluntariness of patients. In Malaysia, the Clinical Trial Informed Consent Form (ICF) shall be reviewed by the ethics committee where the committee itself is comprises of medical background members and lay members. This is crucial as the ICF need to be worded in a layman term so that the patients will not be misled or participating out of undue influence.

The Clinical Trial Agreement (CTA) and its Impact

Fifth, before conducting the Clinical Trial, the relevant party also must have entered into a legally binding agreement known as Clinical Trial Agreement (CTA) which manages the relationship between the Sponsor that may be providing the device or study drug, the financial support and /or proprietary information; the Institution that may be providing data facilities, and/or results; the Principal Investigator and the Study Team that are responsible to conduct the Clinical Trial. The CTA also would describe and acknowledge responsibilities of the relevant party, terms of collaboration, requirements for payment and reimbursement, publication and intellectual property terms, guidelines for dispute resolution, and also terms to ensure the patients' rights and rights of all the parties who involved in the Study are protected such as indemnification, insurance, subject injury /adverse event clauses.[8] As such the Benefit Sharing Agreement proposed by the Act is certainly not relevant to the Industry.

Sixth, implementing the Act in Clinical Trial Industry, will reduce the number of Clinical Trial or Study and also may further delay any Clinical Trial or Study to be conducted in Malaysia as the Industry/ Sponsor must now obtain permit from the relevant authority and enter into benefit sharing agreement with a resource provider and further adhere to additional requirements and procedures which double up the existing procedure and requirements of Clinical Trial in Malaysia (i.e. Informed Consent Form, Clinical Trial Agreement, existing approval from regulatory bodies).Besides that, it may also decrease the innovation in medical industry in providing and improvise the procedure, techniques, medicine and device to be utilised by the patient in Malaysia to provide a better solution to cure their diseases and providing better healthcare. In other words, the patient would be jeopardised from getting alternative treatment/medicine that could prolong their lives. In fact, the implementation of the Act could also reduce the intangible value of research in sharing technology with other countries , recognition from the world for conducting a quality , reliable trial and expanding resources in order to introduce a better treatment, medicine, therapies, procedure and devices to the patient in Malaysia. It is worth to note that any benefits resulting from the Clinical Trial and its applications should be shared with society as a whole and with the global community. The benefits may take in various forms which includes but not limited to giving special and sustainable assistance to and acknowledgement to those that have taken part in the Clinical Trial or Study, public access to quality health care, access to scientific and technological knowledge, building up facilities for research purpose and any other forms of benefit consistent to the above.

Clinical Research Malaysia (CRM) Views

Clinical Research Malaysia (CRM) viewed that, it is best for every Clinical Trial that is to be conducted in Malaysia and other countries to be exempt from the implementation of this Act or any similar Act considering the benefits of it to the country and the people and further due to the adherence of this industry to the fundamental principles, requirement and regulatory compliance and relevant authority in conducting the Clinical Trial or Study in Malaysia. Further, CRM also actively involved in discussing with the relevant authorities in Malaysia on the negative effects of the implementation of the Act to the Clinical Trial Industry. It is a good action that the enforcement body and authorities in Malaysia now support the rights of the people to participate in Clinical Trial and to receive a better healthcare service and medicine by finally giving exemption to the Clinical Trial from the implementation of the Act commencing 2019 .

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Attracting Clinical Research to Malaysia with a Centralised Feasibility Platform

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By Norzaihan Mat Radi (Senior Feasibility Specialist), Tan Bee Ying (Feasibility Specialist) & Audrey Ooi (Head of Business Development) at Clinical Research Malaysia

A feasibility study is a crucial part of the clinical trial planning process. It enables sponsors and contract research organizations (CROs) to identify relevant clinicians who may be interested in a particular study.[1-4] It also provides information on a site's infrastructure, human resources and pool of eligible patients.[1-4] Such information would help these companies strategize to meet timeliness, sample size requirements and regulatory and ethical conditions, as well as plan for potential challenges.

As clinical research involves multiple stakeholders, the presence of a single point of contact can improve communication, simplify processes, and reduce delays.[5,6] This centralized approach is particularly useful for feasibility and site selection processes.[6] In Malaysia, Clinical Research Malaysia (CRM), a not-for-profit government-owned organization established in 2012 to nurture an ecosystem that supports industry sponsored research in the country, offers sponsors and CROs a one-stop contact point for feasibility requests, access to the public hospital network of investigators, and other services.

This review will present the role of CRM's centralized feasibility service in attracting sponsors and CROs to Malaysia.

The importance of rigorous feasibility studies

Pre-feasibility is information that is collected for preliminary, higher level assessments which allows sponsors and CROs to make decisions at a national and global level. Such enquiries include general questions on standard of care, drug registration status, epidemiology, and estimated patient pool of a particular therapeutic indication. A full feasibility study is a complete documentation of individual sites which may include a confidential disclosure agreement, protocol synopsis and site assessment questionnaire.

About 35% of delays in clinical trials are attributed to patient recruitment with one in five investigators unable to recruit a single patient.[4] As non-active or under-performing trial sites can increase the cost of conducting a clinical trial by 20% or more,[7] rigorous feasibility studies conducted in multiple centres are recommended.[8] But conducting thorough feasibility assessments and selecting appropriate sites may be time consuming, and delay in these preliminary processes will jeopardise study milestones.[7] Therefore, if feasibility processes in individual countries can be centralized with a single point of contact for sponsors and CROs, delays and redundancies may be avoided.[5,6]

35%
of delays
in clinical trials are attributed to patient recruitment

Cost of conducting a clinical trial
increased by
20% or more
from non-active or under-performing trial sites

Leveraging the strength of a nationwide access to public hospitals

One of the challenges in conducting feasibility studies is maintaining an updated database of principal investigators. The bulk of studies in Malaysia are conducted in government hospitals where doctors are transferred periodically. Therefore, data built on individual company databases can be outdated, thus misguiding and delaying feasibility approaches.

In Malaysia, CRM is the common link for various stakeholders which include sponsors, CROs, private and public doctors from universities, health clinics and hospitals, as well as the regulatory agencies and ethics committees. It is a centralized government-owned body that manages and overlooks Malaysia's entire clinical research ecosystem.[9] The detailed objectives of CRM are discussed in a prior article.[10] As a single

point of contact for sponsors and CROs and with presence in 33 clinical research centres within public hospitals throughout the country, CRM is vital in streamlining and accelerating feasibility studies in Malaysia.

Evolving to offer complimentary, centralized feasibility management

As CRM receives a variety of enquiries (Table 1) including pre-feasibility and full feasibility requests across all clinical therapeutic areas from both sponsors (pharma, medical device, biotech) and CROs worldwide, the Ministry of Health, Malaysia through CRM, established a centralized feasibility service. This service which is offered complimentary to sponsors and CROs, capitalizes on a comprehensive updated internal database of investigators, and enables outreach to a wider range of investigators and sites.

Previously, the sponsors and CROs conducted their own feasibility assessments and contacted individual sites on their own.[11] Separate databases based on a company's own experience, may not always be updated, and information such as transfer of clinician, changes in site personnel, and regulatory changes may be missed.[11]

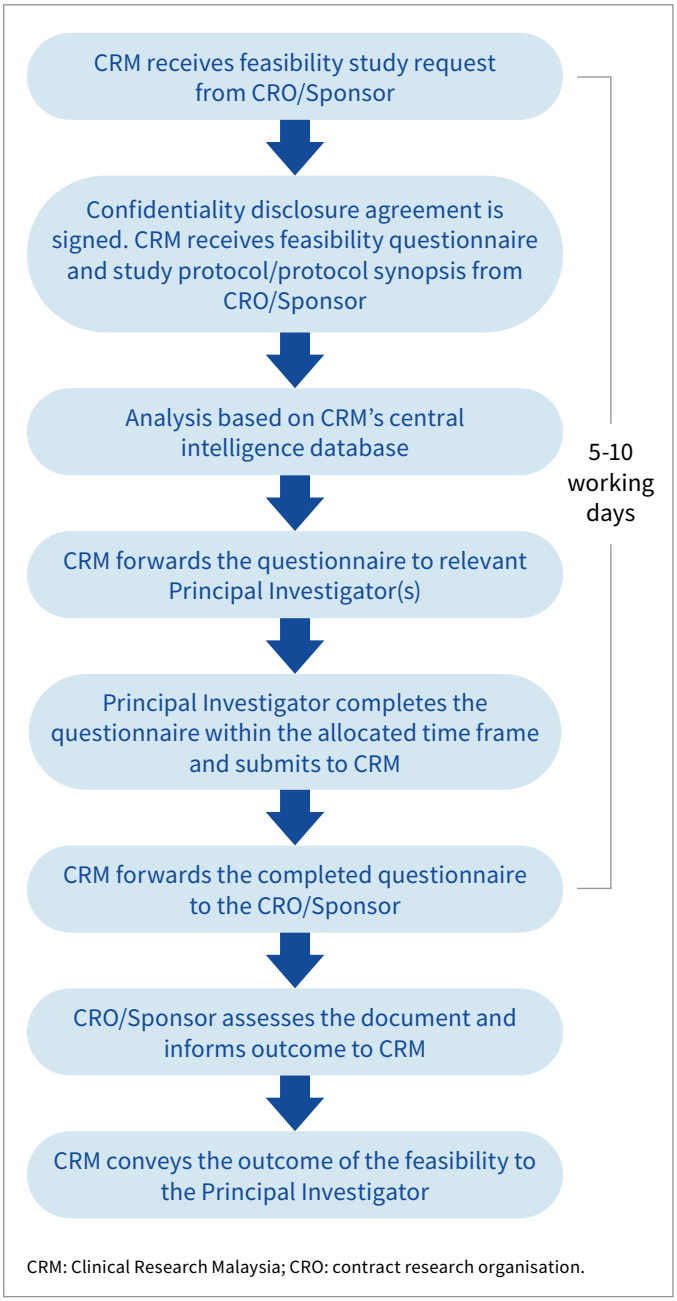
A centralized process leads to centralized knowledge of the research environment which benefits CROs and sponsors engaging the service. A central database which incorporates data on a site's performance and experience in recruitment and compliance provides more insight into how the site may perform in future trials.[1,7] And as a single point of contact, the standardized processes lead to streamlined communications which reduces delay and confusion on the ground. As a result, the turnaround time is shorter than if a sponsor or CRO were to approach individually.

As CRM has a strong network, good rapport with investigators, and is familiar with ground level capacities of sites, poor site selection is less likely. Sites are mapped according to disease to enable the right sites to be approached for a specific patient pool in future. The sites are also mapped to track investigators who were overwhelmed, conducting competing trials, or transferred to ensure that only available investigators are contacted for upcoming trials. Such data would help narrow down the investigators who will give positive responses, thus reducing the time needed for feasibility studies.

When the feasibility team at CRM receives a feasibility questionnaire, a thorough analysis based on CRM's central intelligence database is done (Figure 1). The questionnaire is then forwarded to relevant investigators. The process from the time CRM is approached to conduct a full feasibility assessment to the time CRM sends the completed questionnaire back to the company would take 5–10 working days. Pre-feasibility enquiries would take between one and five days depending on the complexity of the questions.

Optimising Feasibility in Clinical Trials with Clinical Research Malaysia's Centralised Process

Figure 1. Clinical Research Malaysia Clinical Trial Full Feasibility Process



CRM: Clinical Research Malaysia; CRO: contract research organisation.

In addition, the feasibility specialists help interested potential investigators to address the queries and submit the completed feasibility questionnaire to the enquiring company. They provide technical consultation and organize meetings between investigators and CROs. Information is also compiled when investigators reject feasibility requests to understand their reasons for doing so.

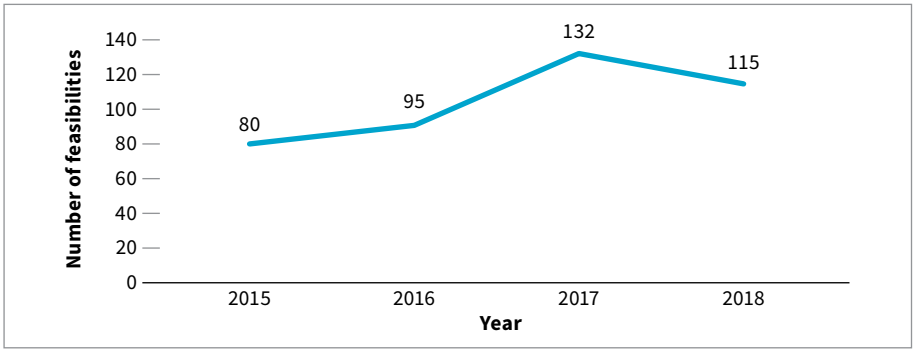
Centralized service, a key attraction for sponsors and CROs

A centralized feasibility management service is a key attraction for sponsors and CROs,5 as the information from feasibility studies determines the suitability of Malaysia for a particular trial and promotes the capability of the sites to new international companies. The one-stop national feasibility model improves efficiency and timelines, as well as reduces the financial, administrative, and human resource burden of sponsors, CROs and investigators.

Sponsors and CROs are becoming more interested in Malaysia after the introduction of centralized feasibility, with full feasibility requests received by CRM increasing between 2015 and 2018 (Figure 2). There were also a five-fold increase in sponsors and an almost three-fold increase in CROs using CRM's services in 2018 compared to 2014 (Figure 3). Majority of these companies are international companies (85%).[5,11]

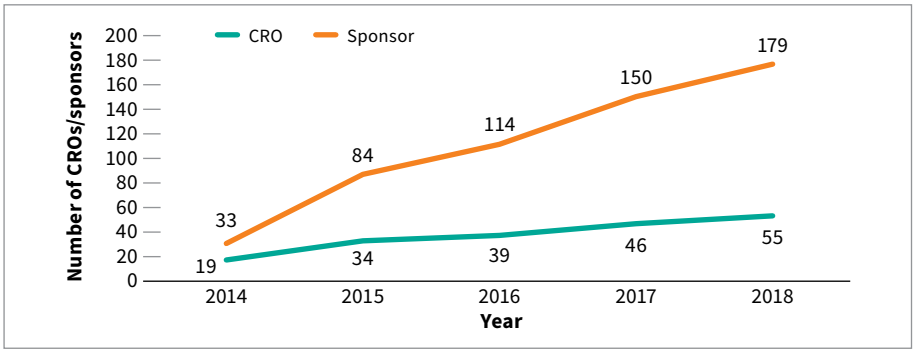
Rise in the use of Clinical Research Malaysia's services, particularly the clinical trial feasibility assessments

Figure 2. The increase in full feasibility requests received by Clinical Research Malaysia from sponsors/CROs



CRO: contract research organisation.

Figure 3. Growth in the number of CROs/sponsors using Clinical Research Malaysia feasibility services



CRO: contract research organisation.

In addition, feasibility assessments are complimentary, thus contributing to the overall cost-effectiveness of conducting a trial in Malaysia.

Conclusion

Clinical Research Malaysia's model as a one-stop national center is a primary factor for the expansion in Malaysia's clinical research industry in the last few years. The growth in sponsors and CROs is made possible through a centralized feasibility team coordinating and overseeing communications with sites. Thus, on a nationwide perspective, a centrally managed feasibility structure is an attractive alternative for sponsors and CROs looking to enhance efficiency and width of a feasibility outreach, avoid redundant processes and promote a more accurate assessment of Malaysia's capabilities.

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Do you or someone you know have *medical conditions?*

such as cancer, diabetes, heart disease and others

CRM
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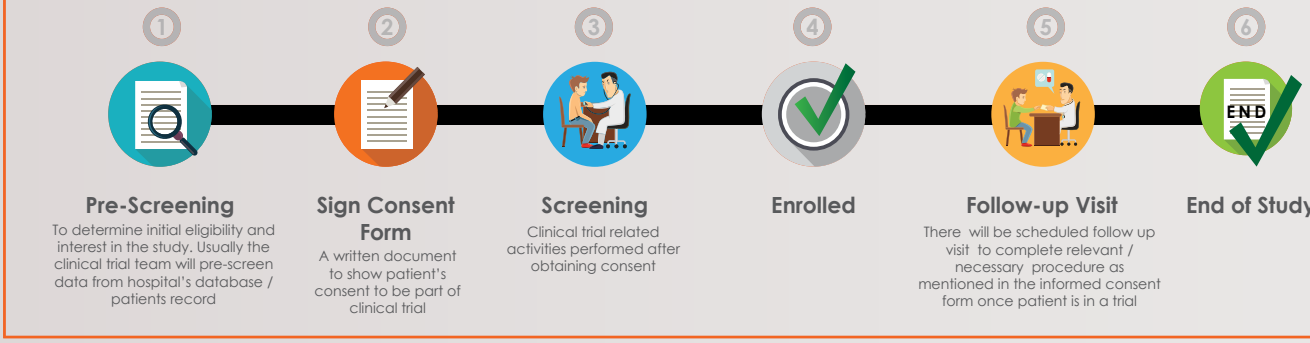
PARTICIPATING IN A CLINICAL TRIAL - What you need to know



For more information, please send us a message via Whatsapp at 016-320 0376 or email to contact@clinicalresearch.my

CRM IN PHOTOS

Meeting Mr Miyasaka, Head of Welfare Attache from the Embassy of Japan

7 Jan

Meeting with Geneaid Biomed (Taiwan)

10 Jan

Meeting with SunMed for Early Phase Clinical Research

15 Jan

Meeting delegation from Indonesian Ministry of Health and the National Institute of Health Research and Development (NIHRD)

21 Jan

Meeting with Dr Hishamshah Mohd Ibrahim

23 Jan

Meeting with Dr Goh Siew Lee & Ms. Serena Chan from Syneos Health

23 Jan

National Conference 2020 and Clinical Operation Training

29 Jan

Meeting with Medi Radio Malaysia and Universiti Putra Malaysia

3 Feb

Asia Pacific Economic Cooperation

21 Feb

Site Visit to National Cancer Institute and HKL

24 Feb

Meeting with Malaysia Bioeconomy Development

24 Feb

Info Day Medical University Malaysia

26 Feb

GCP Refresher Workshop

13 Mar

Meeting with Malaysian Health Diplomacy Foundation and Saora Industries

12 Jun

Meeting with Tan Sri Dato Lim Yew Loong and Sinopharm representatives

12 Jun

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D-26-06, Menara SuezCap 1, KL Gateway, No. 2 Jalan Kerinchi,
Gerbang Kerinchi Lestari, 9200 Kuala Lumpur, Malaysia.
T: +603-7931 5566 | **F:** +603-7931 9940 | **E:** contact@clinicalresearch.my

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