BY CLINICAL RESEARCH MALAYSIA

CRM Bulletin

ISSUE 24 | Jul - Dec 2022

CONVERGING STAKEHOLDERS THROUGH CRM TRIAL CONNECT 2022

RESEARCH PERSONALITY
DR WONG KIT CHAN

- FEATURED SITE
  HOSPITAL SULTANAH FATIMAH MUAR
- HIDDEN GEMS IN KLINIK KESIHATAN

About Clinical Research Malaysia

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

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

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

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

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

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CLINICAL RESEARCH MALAYSIA
Your Global Solutions in One Nation

From The CEO's Desk

Warmest welcome to CRM Bulletin Issue 24!

Just in a blink of an eye, the year 2022 has come to an end. To say it has been a fruitful year would be an understatement, with physical and virtual meetings, workshops, trainings, international conference presences, and the star of the show, CRM's very first conference!

The CRM Trial Connect 2022 conference that was held in October proved to be a great success, and it was all thanks to the organizing committee and the participating delegates, faculty and sponsors that made this happen. We believe that it is the ultimate platform to gather all stakeholders together and share their experiences and valued insights on the flourishing clinical research ecosystem; all whilst expanding their network bubble. The conference had the Minister of Health as well as Director General of Health alongside field experts sharing their perspectives on clinical research growth, and esteemed faculty consisting of experts from Malaysia's clinical research ecosystem, enlightening on the growth and insights of global clinical research within the nation. CRM also showcased its continuous collaboration with its Japanese counterparts with the inking of the Memorandum of Understandings with Remedy & Company Corporation, National Centre for Global Health and Medicine, and continued partnership with the National Cancer Centre, Japan.

2022 also marks a decade since the establishment of CRM. Looking back at the journey undertaken, it truly fills me with pride to see how much the organisation has grown over the year. With the company's formation objectives all achieved in 2020, it's now time for the organisation to evolve to new goals and visions that would further encompass the growth of sponsored research within the country, guided by principles of HUMANITY, STABILITY and SUSTAINABILITY.

Through the values of HUMANITY, CRM continues to attract more sponsored research into the country to provide access and treatment options to patients, contribute to the discovery of new and better therapeutics, while at the same time providing a stable and progressive career development to CRM's employees.

The value of STABILITY is reflected in our consistency in delivering the key metrics of clinical trial recruitment and quality conduct, as well as developing human capital through various training and development programs. With 2023 KPIs in place, CRM strives to continue growing sponsored research within the country, marking a distinct footprint in global clinical trials. Close engagements with stakeholders are not to be forgotten as well, with more of partnerships to forge in year 2023, especially following the discussions and engagements we've had with our clients in the last quarter.

Finally, SUSTAINABILITY is focused in working towards achieving Vision 2026, implementation of operational excellence, developing new business income and steadfast in establishing CRM as a global trusted research management organization. All this converge to CRM delivering studies with speed, quality & reliability. CRM aims to continue its work in further enhancing the nation's capabilities in early phase research through its Phase 1 Realisation Project 2.0. Early phase research also bears exciting tidings in Malaysia, with a First-in-Human (FIH) study slated to begin in 2023 at Sarawak General Hospital, and National Pharmaceutical Regulatory Agency having expanded to accepting FIH biologics (except Cell & Gene therapy Products) applications.

That being said, I would like to thank everyone in CRM who has been working hard in propelling Malaysia as the preferred destination for sponsored research. Simply put, we are very proud of how far CRM has come and achieved and cannot wait for what is in store for us in the coming future! Thank you for giving us this opportunity and we look forward to giving more in the upcoming years!

Dr. Akhmal Yusof
CEO, Clinical Research Malaysia

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CRM'S GUIDING PRINCIPLES

HUMANITY

- Meeting unmet medical needs through clinical research
- Raising public/ patient awareness & engagement
- Corporate social responsibility & work life balance

STABILITY

- Steadfast in clinical research initiatives
- Consistency in clinical research performance
- Continous engagement with stakeholders
- Human capital development

SUSTAINABILITY

- Globally trusted research management organisation
- Operational excellence & vision 2026
- Organisational culture that practices good governance & adherence to code of conduct

CRM NEW SERVICES

CRM
CLINICAL RESEARCH MALAYSIA

CLINICAL TRIAL ADVERTISEMENT SERVICES

PLATFORM

- Facebook & Instagram
- Targeted audience approach via Sponsored Ads.

Contact: bd@clinicalresearch.my

CRM
CLINICAL RESEARCH MALAYSIA

STUDY DRUG DESTRUCTION SERVICES

- Provide proper and adequate handling of study drug disposal
- Outsourced vendor with certified ISO 9001:2015, ISO 14001:2015 and ISO 45001:2018
- Service provided complies with strict Standard Operating Procedures & Good Clinical Practice

Contact: komala@clinicalresearch.my

HIGHLIGHTS

Regulatory Inspection Workshop

20 July & 23 November 2022 – CRM successfully conducted 2 workshops on Preparation for Regulatory Inspection in 2022. With speaker Mr Oh Chen Wei (NPRA) sharing his insights and experience, workshop attendees gained further perspective on regulatory inspection at sites.

Nurturing New Talents in Sponsored Research

12 August 2022 – CRM organized its first physical Nurturing New Talent in Sponsored Research since the pandemic in Hospital Kuala Lumpur and had great turnouts from various healthcare institutions. Dr. Albiruni A. Razak, Medical Oncologist from Princess Margaret Cancer Centre, Toronto shared his insights and expertise into the clinical trials venture.

Done and dusted! TIPS training

4 - 22 August 2022 – CRM has finally completed its 6 sessions of training with the theme 'B2B- Back to Basic'. In collaboration with Janssen team, the training was conducted to ensure only the best quality and clinical operations practices are adapted among study coordinators.

GCP Refresher Workshop made 2 comebacks in H2 2022

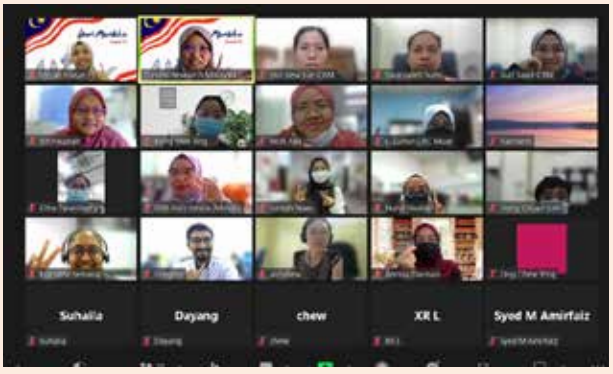
30 August & 14 December 2022 – The 3rd & 4th series of GCP Refresher Workshop was successfully conducted with the support of study investigators and research teams all around. Thanks to Ms Yoong Kai Shen for her contribution and sharing session from the AE/SAE Management.

Visit with Dr Aaron Neal from NIAID, NIH

7 September 2022 – CRM was delighted to host Dr Aaron Neal, who was at CRM for 2 weeks, to further understand better on the clinical research ecosystem in Malaysia. Amongst the sites that was visited were Sunway Medical Centre, Hospital Sg Buloh, Hospital UiTM, DNDi, Hospital Ampang and University Malaya Medical Centre.

ESMO Congress 2022

11 September 2022 - CRM was thrilled to have participated in ESMO in Paris Expo Porte De Versailles, where connections were made with industry leaders and researchers in oncology.

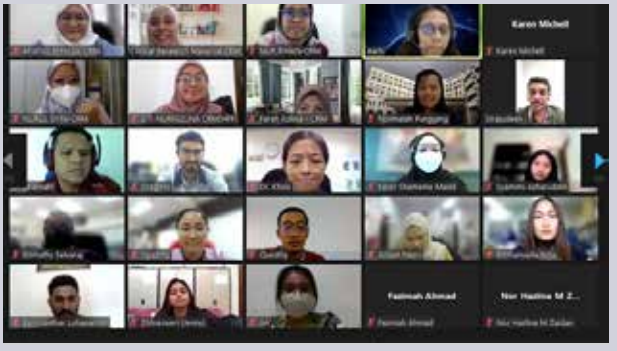


2nd & 3rd Patient Recruitment and Retention Workshop

22 September & 24 November 2022 - Kudos to CRM for successfully conducting its 2nd and 3rd Patient Recruitment and Retention Workshop with various speakers sharing their knowledge. Our hope is that the method and strategies shared will be applied during recruitment activity.

NCCR 2022

19 October 2022 - Hearty congratulations to Institute Clinical Research and Datuk Kalaiarasu Peariasamy for the successful 15th NCCR launch. The conference saw great turnouts highlighting impactful research that drives the health policy of the nation.



Protocol Compliance Workshop Series 1 & 2

28 July & 26 October 2022 – Ending the year with yet another series of workshops that includes CRM's study coordinators. We thank speakers from MREC and PPD (Thermo Fisher Scientific) for their valuable time and knowledge, in facilitating this program.

Visit to Princess Margaret Cancer Centre, Canada

8 December 2022 – CRM along with its board member, Director General of Health, Tan Sri Dato' Sri Dr Noor Hisham Abdullah, met with the Princess Margaret Cancer Centre (PMCC) leadership team during their visit to the facility. The program was purposed to further understand PMCC's expertise in clinical research as well as to enhance collaborative opportunities with the centre.

IN THE NEWS

CRM Trial Connect 2022

In October 2022, Clinical Research Malaysia (CRM) organised its first conference, the CRM Trial Connect, in Kuala Lumpur. The conference was aimed to showcase Malaysia's capabilities, experiences and outstanding achievements in multinational clinical research and sponsored clinical trials. Attended by over 400 delegates, exhibitors, and faculty members, the 2-day hybrid conference gained many tractions and received positive response from crowds consisting of stakeholders, study coordinators and investigators all around as it provided an excellent platform to re-establish old and develop new connections and networks with clinical research industry players, while serving as a foundation in understanding the country's clinical research landscape and potential.

The opening session were led by both Dr Akhmal Yusof, Chief Executive Officer of CRM and Datuk Dr Kalaiarasu M. Peariasamy, Director of Institute for Clinical Research (ICR) who presented respectively on CRM's decade journey in bridging clinical trials with stakeholders and investigators globally as well as on ICR's key research projects and collaborations that have shaped the health policy decisions in Malaysia. The conference was officiated by YB Khairy Jamaluddin, then Minister of Health who shared on the importance of conducting quality ethically conducted clinical trials and research for early access of safe effective therapies to patients. The pinnacle of the opening was the forum which was participated by the Minister along with key experts in clinical research. The panel discussion saw much pertinent sharing on opportunities, challenges, and vision for this robust and thriving field.

Another highlight of the conference were the partnerships formalised and acknowledged with several Japanese organisations/ institutions, including a new partnership with National Centre for Global Health and Medicine and renewal of partnership with Remedy & Company Corporation. Also present was the National Cancer Centre of Japan that have an ongoing collaboration with CRM in early phase cancer trials. The whole ceremony was witnessed by both YB Khairy Jamaluddin and HE Takahashi Katsuhiko, Ambassador of Japan to Malaysia.

The CRM Trial Connect conference had over 30 speakers who presented in various sessions, one including on vaccine development and access, which showcased Malaysia's plan of action to be self-sufficient in vaccine R&D and the success of Hospital Sultan Abdul Halim delivering a global vaccine trial. Top therapeutic areas such as oncology and cardiology were featured among some sessions as well, with renowned investigators sharing research achievements and trial site capabilities. Another highly sought-after session was on early phase clinical research which included speaker Dr Albiruni Razak from Princess Margaret Cancer Centre (Canada), one of the global top cancer research centres, to speak on the intricacies of First-in-Human trials. Hearing first-hand of the experience he faced was eye-opening for the delegates in understanding better of the oncology clinical trials background.

In lieu of the conference, it was clear that partnerships between public, academia, NGOs, and private stakeholders hold a significant role in enabling stakeholders to harness the collective strengths within each sector while gaining insights and developing processes to improve existing limitations and challenges within individual sectors. In addition, partnerships at the national level are without a doubt important. But it is just as essential as the immense value provided by regional and international collaborations. Another note-worthy point is that investment is a vital aspect of clinical trials in ensuring Malaysia reaches its goal of becoming a leading clinical trial hub. As far as it goes, stakeholders have the government undivided support seeing this through by bringing Malaysian Investment Development Authority (MIDA) to ensure the clinical research setting in Malaysia bloom.

The last day of the conference brought important key players to discuss in-depth on how to balance science and regulations in works for better access to innovative treatment in Malaysia. The audience saw an enlightening discussion and everyone had a better understanding of the clinical research ecosystem in Malaysia. The conference was a great success, thanks to the collaboration of sponsors and support of the delegates from all around. Closing the conference, the Director General of Health, Tan Sri Dato Seri Dr Noor Hisham Abdullah shared his remarks, encapsulating the essence of the 2-day conference.

392	101	12	10
Delegates & Exhibitors	Organisations	Countries	Booth Exhibitors

Accelerating Malaysia in Global Clinical Trials

CRM TRIAL CONNECT 14-15 OCT 2022

43 Faculty Members **32 Presentations** **11 Sessions**

2 Forums **2 Keynote Adresses**

New Clinical Research Partnerships Aimed to Further Enhance Malaysia's Footprint in Global Trials

KUCHING, 5 September 2022 – Novartis Malaysia, together with Clinical Research Malaysia (CRM) on behalf of Sarawak General Hospital (SGH) inked a Memorandum of Understanding (MoU), making SGH a preferred clinical trial site to conduct Novartis sponsored trials in Malaysia. With this MoU, SGH will now become a centre of excellence in the country for clinical trials.

The signing was witnessed by then Minster of Health, YB Tuan Khairy Jamaluddin alongside Professor Dato' Sri Dr Sim Kui Hian, Sarawak Deputy Premier and Minister of Public Health, Housing & Local Government Sarawak, Dr Ooi Choo Huck, Sarawak Health Department Director, and Dr Ngien Hie Ung, Hospital Director, Sarawak General Hospital.

Novartis has brought over 60 sponsored research into Malaysia since 2015, with 38 trials invested just in 2020, making them the top contributor to clinical trials in Malaysia. One of Novartis's visions is to reimagine medicine, which in turn, improves people's lives and strengthens Malaysia's healthcare ecosystem.

TORONTO, 7 December 2022 – Clinical Research Malaysia (CRM) achieved a new collaborative milestone with the signing of a Memorandum of Understanding (MoU) with the Princess Margaret Cancer Centre (PMCC). PMCC is one of the top 5 and largest cancer research centres in the world and focuses on all three areas of research: basic, translational and clinical research.

The inking of this MoU spells cooperation in the area of clinical, academic and research opportunities at both organizations. This will also entail education and training opportunities including fellowship attachments, staff and patient education. Other initiatives also aimed at promoting and enabling collaboration, innovation and knowledge exchange to advance cancer care control in both countries.

The MoU was witnessed by the Director-General of Health Malaysia, Tan Sri Dato' Seri Dr. Noor Hisham and signed by Dr Akhmal Yusof, CEO of CRM and Dr Keith Stewart, Vice President, Cancer and Medical Director of the Princess Margaret Cancer Program, UHN who is also the Regional Vice-President, Toronto Central South Regional Cancer Program, Ontario Health.

PUTRAJAYA, 23 December 2022 – Clinical Research Malaysia (CRM) signed a charter agreement with Syneos Health, the only fully integrated biopharmaceutical solutions organization purpose-built to accelerate customer success, formalizing the inclusion of CRM-affiliated clinical research sites under the Syneos Health Catalyst Program.

The Syneos Health Catalyst Program brings together clinical research sites and industry partners to deliver consistent quality in clinical trials. Sites under the program have the opportunity to participate in an increased volume of clinical trials as well as harness best practices and insights from other clinical research sites across the globe. With the inking of this partnership, research sites in Malaysia will form Syneos Health's first Catalyst Site Network in the Asia Pacific region. Sites within the network would benefit from increased access to clinical trials managed by Syneos Health in addition to improved efficiencies in study operations.

RESEARCH PERSONALITY

Dr Wong Kit Chan

Psychiatrist, UD 56 , Hospital Tuanku Ja'afar, Seremban

About Dr Wong Kit Chan

Dr Wong Kit Chan graduated with honours in 2007 with a three-degree programme of MB, BCh, BAO (Hons) from University College Dublin (UCD). She initially served as a House Officer in Hospital Raja Permaisuri Bainun and later as Medical Officer in Hospital Teluk Intan Perak at the Paediatrics department (2008-2009) and General Psychiatry (2009-2011). Following this, Dr Wong Kit Chan obtained her postgraduate degree in Psychiatry from Universiti Kebangsaan Malaysia in 2015 and was stationed at Hospital Tuanku Ja'afar, Seremban in Mental Health and Psychiatry department until now. With up to 11 clinical research studies and overseeing the Research Unit at HTJ, she also received numerous awards for her achievements and outstanding performance along the way.

When were you first involved in clinical research and how did you come across a clinical research opportunity?

I was first involved in clinical research during my Master postgraduate training in 2013, as a requirement for thesis writing. I had the opportunity to be first involved in ISR in 2015 when I was invited by my then HOD, to be part of the first psychiatry ISR in my hospital. The clinical trial turned out to be a huge success and we were awarded the top recruiter in Malaysia, which gave us a very encouraging and positive start in ISRs.

Have clinical trials changed your practice and management of patient care? If so, how?

Definitely. Since my involvement in clinical trials, my perspective on patient care has changed tremendously. I am always encouraged that there is increasing hope for psychiatric patients as more treatment options are sprouting up. Being involved in clinical trials has opened my door to different and new treatment options for psychiatric patients, which may not be as diverse and numerous decades ago. The increasingly active involvement of Malaysia in clinical trials in psychiatry has given renewed hope to the rising tide of psychiatric patients.

The field of psychiatry is very different compared to other branches of medicine. The care providers as well as patients and their family must deal with the stigma surrounding psychiatric illnesses. Clinical trials in psychiatry do not only bring in new treatment opportunities, but also serve as a platform to spread awareness about mental health and to reduce stigma surrounding the diagnosis of psychiatric illnesses. Hopefully patients and family are more willing to come forward for treatment with the advanced treatments becoming more readily available and accessible.

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

Manpower is one of our biggest challenges. We started with a small team of 3 investigators including myself and one study coordinator from CRM. Over the years, we have now grown to a strong team of 5 investigators and 3 study coordinators. I have no other words to describe the values of my team of investigators and study coordinators except for pure dedication and full commitment. The research unit of psychiatry in HTJS will not be standing strong as where we are now without this solid backing team.

Another challenge that I faced was having to take up the role of Principal Investigator in our second study due to the lack of manpower back then. Being a junior psychiatrist during that time, I braved myself to take up the role of Principal Investigator, albeit with slight self-doubt, having only had experience as a Sub-I in my first clinical trial. That turned out to be my best decision ever, as with that role, I gained a lot of experience and knowledge on how to handle clinical trials as a PI. Since then, I have been invited to be the Coordinating PI for numerous clinical trials and our site has also gained recognition globally as a top recruiter for various clinical trials. To date, I am encouraging my fellow specialists to be involved in clinical trials and training them so that they can also take up the role of a PI.

Lastly, time management is pivotal in conducting any clinical trial. To ensure the success of a clinical trial, time and commitment must be poured in willingly. My team and myself often had to work beyond office hours to fulfil the necessary research work.

What drives and motivates you to conduct clinical trials?

I am driven by the hope and passion to help psychiatric patients recover and return to their normal functioning self. I view clinical trials as an excellent platform to transform how psychiatric illnesses are being treated and to create new modalities to treat these illnesses to change patients' lives. That, for me, is the mission of clinical trials.

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

Fulfilling. The sense of fulfilment and accomplishment that comes with patients' improvement and recovery with new treatment options is something that I could only experience first-hand with clinical trials.

In the research field of Psychiatry/Psychology Disorders, what are the biggest challenges and what are the changes you would like to observe?

The biggest challenge for me is the stigma surrounding psychiatric illnesses. I have come across patients and caregivers who refused participation in clinical trials due to not wanting to have their psychiatric illness made known to others. With the increasing cases of psychiatric illnesses over the years and especially during the Covid-19 pandemic, my hope is that more focus will be given to the field of psychiatry, particularly in clinical trials. Clinical trials do not only bring new hope in treatment opportunities, but they also serve as a platform to increase the awareness of psychiatric illnesses and reducing the stigma associated with them.

> "I am driven by the hope and passion to help psychiatric patients recover and return to their normal functioning self"

What is the gap you observe in the research interest when considering Psychiatry/ Psychology Disorders in Malaysia?

There is a huge gap in the research industry in the field of Psychiatry as compared to other branches of medicine. With the increasing awareness of mental health and with it, the emergence of a dire need for new treatment opportunities to be made available to patients; bridging this gap in the research industry is irrefutably of crucial importance.

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

I wish to see Malaysia as an outstanding clinical trial hub highly sought after by global stakeholders. We have all the potential to excel in translational research in each of our own field, and with CRM's helping hand, it is in due time that Malaysia is propelled to the forefront of clinical trials in the global arena. Clinical trials open new doors to novel and highly impactful solutions for psychiatric illnesses, and these are much needed in this era of increasing mental health crisis.

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

Clinical trials are what shaping the healthcare of the future; therefore, policy makers should make clinical trials the top priority in Malaysia's healthcare system. A dedicated research centre in the form of facility, equipment, manpower and funding must be made available in major hospitals to make clinical trials more accessible and to encourage active participation in clinical trials. Besides, researchers who achieve outstanding performances in clinical trials should be recognised and rewarded as a form of motivation. Ultimately, clinicians who have no prior experience in clinical trials ought to take a leap of faith and reward themselves with the journey of being in one; a clinical journey which will undoubtedly be immensely fulfilling.

Dr Wong Kit Chan in her office

Standing (L-R): Maisarah Noor, Siti Hawa Md Yusuff, Dr Wong Kit Chan, Magdalene Mary a/p Mayappan, Engku Fatimah Syairah Engku Safruddin, Nur Farahin Ahmad Faishal (not in pic) - CRM Study Coordinators

> "Clinical trials in psychiatry do not only bring in new treatment opportunities, but also serves as a platform to spread awareness about mental health and to reduce stigma surrounding the diagnosis of psychiatric illnesses"

HIDDEN GEMS IN KLINIK KESIHATAN

With over 2000 sponsored trials since 2012, Malaysia has proved its capabilities in conducting trials involving various therapeutic areas. In this issue, CRM would like to highlight on the hard work of Principal Investigators from Health Clinics who are part of the backbone of clinical research in Malaysia. Let's hear it from them on their journey into this industry.

Dr Siti Shafiatun Mohsin
Family Medicine Specialist

Head of Clinic,
Klinik Kesihatan Cheras,
Kuala Lumpur

During my job at Outpatient department HKL, one of the CRC staff approached me to be the Principal Investigator in a clinical trial which ultimately became my stepping stone into this field. Since then, I had continued my rewarding journey and involved in more interesting clinical trials.

Participating in clinical trials would empower our patients to indulge in their own self-care. Patients could contribute and be part of advancement in Medical Science specially to find better treatment of illness. They could also gain proper knowledge about their conditions and develop better relationship with health care providers.

Sense of achievement and being part of scientific knowledge and evidence had motivated me to be involved in clinical trials. Finding new, better and safer treatment for patient care will help in the advancement of medical science. Recognition of my efforts also had driven me to continue as a researcher.

I would recommend my peers to take up clinical research because it would be a good recognition for their effort in local and international level. By contributing and assisting in bettering patients care, it would bring a sense of reward for oneself.

> "Finding new, better and safer treatment for patient care will help in advancement of medical science"

Dr Wong Ping Foo
Family Medicine Specialist

Head of Clinic,
Klinik Kerajaan Cheras Baru, Kuala Lumpur

My exposure to research component during my Family Medicine Postgraduate Training Programme has sparked my interest in conducting research and clinical trials. It has provided and equipped me with a solid foundation for me to grow further. Right after I passed as a Family Medicine Specialist, I sat for Good Clinical Practice certification and moving forward, I began my journey with clinical trials in 2016.

Family medicine is rooted in science and therefore evidence-based management has always been one of the bases in my approach. By conducting clinical trials, it has further strengthened the contribution of science in Primary Care for the betterment of patient care. At the same time, my patients have the option of getting new tests, devices, vaccines, and medications.

Family Medicine/Primary Care is special because of the wide spectrum of diseases encountered within the broad age group. In which, it provides a rich platform and positive environment for the conduct of clinical trials. It also helps me to widen my horizon with the latest medical advancements and updates. By involving in clinical trials, it enhances my accountability and leadership apart from contributing to the nation's growth. I would like to take this opportunity to acknowledge and give the most credit to my dedicated team whom without them, I would not be able to write in this bulletin column. Lastly, conducting clinical trials in Primary Care is certainly feasible and possible!

Dr Noor Harzana
Family Medicine Specialist

Klinik Kesihatan Pandamaran, Selangor

My first exposure to ISR medical research was in 2016, when I became an FMS attached to Pandamaran Health Clinic. The Consultant FMS and Head of the clinic at that time was Dr. Ruziaton Binti Hasim, who was a great mentor to me and ultimately inspired me to be in clinical research. Under her guidance, I had the opportunity to be involved in interventional dengue vaccine studies (2016), pneumococcal vaccine (2018), and transcutaneous bilirubinometer (2019). I was also highly inspired by my supervisors, Prof Dr. Khoo Ee Ming and Prof Dr. Tan Maw Pin during my postgraduate training at Universiti of Malaya because clinical research looks to improve the quality of life for people.

People should take the opportunity to participate in clinical trials because they get to help in contributing to move science forward as part of national contribution. Others participated to receive the newest treatment from clinical trials. Clinical trials also offer hope for many people and improve healthcare services by raising standards of care of treatment and opportunities to help researchers find better treatments for others in the future.

Pandamaran Health Clinic is a great workplace, blessed with a dedicated research team. Despite the difficulties during the clinical trials, we plough through as a team through identifying the challenge and providing solutions. Through clinical trials, we learnt the best practice in clinical documentation as well as good networking with patients, stakeholders, and the community. I would encourage my colleagues to join these clinical trials as it is part of self-development, medical career development and expertise.

Dr Kow Fei Ping
Family Medicine Specialist

Klinik Kesihatan Jalan Angsana, Bandar Baru Air Itam Pulau Pinang

My first opportunity to this field was back when I was a Master Programme Trainee in university when we had the chance to help out with subjects' recruitment for clinical research for a senior lecturer. My patients influenced me the most as they encourage me to always find treatment and modalities that may potentially benefit them. Besides that, my colleagues' motivation, enthusiasm and encouragment is what fuels me everyday to be in this field. I also find myself to be the biggest influence on me as I have to ensure that I'm always a clinically relevant physician to my patients.

I would definitely recommend my colleagues to take up clinical research, as it is an opportunity to explore and understand the possible benefits, safety and effectiveness of drugs and treatment modalities in our daily clinical practice. On the contrary, it may also shed light on what may or may not work on our patients.

Involvement in clinical research may be challenging and demanding in our hectic day work. Nevertheless, it does help provide a little excitement and a sense of accomplisment to our daily clinical work too.

> **People should take the opportunity to participate in clinical trials because they get to help in contributing to move science forward as part of national contribution**
>
> **Dr Noor Harzana**

Dr Chang Li Cheng
Consultant Family Medicine Specialist

Head of Clinic
Klinik Kesihatan Kuang,
Rawang, Selangor

Dr Noor Mikraz Mohd Isa
Family Medicine Specialist

Klinik Kesihatan Seremban 2,
Negeri Sembilan

Back in 2013, a senior of mine requested me to take on a clinical trial course. Without giving much thought, I took it on a whim and got the certificate around 2013. However only in 2017 is when I finally decided to dive into this whole new sector of work. As luck would have it, my senior asked me to join her asthma observational study. Under her wing as Co-Investigator, my passion built up even though we only had a 5-man team. My biggest confidence booster would be when each research targets were achieved way before their deadlines. That's when Hospital Selayang's CRC took me as an investigator for their trials.

The thing that motivated me to conduct these trials is my need to serve the community. The heart aching amount of people who still die from dengue every year is the reason why I put myself on the line of clinical trials. Not to mention, I must be a great mom and role model for my son as he aspired to be a scientist. It was paramount for me to let them know that nothing can't be achieved if you have the will.

In a way, clinical trial made me more meticulous in documentation, time management etc. The amount of activities to be performed in accordance to clinical trial protocol is virtually endless. Although it can be daunting at times, they have taught me a lot in terms of designing, arranging, and organizing work. I would recommend my peers to take up clinical research but for those who are not confident, I can always offer a helping hand. By guiding them, I hope to encourage more of my peers, doctors and alike to take part in clinical research. Just imagine the untapped potential of Malaysia's medical sector if all medical facilities have have their own clinical research centres all around.

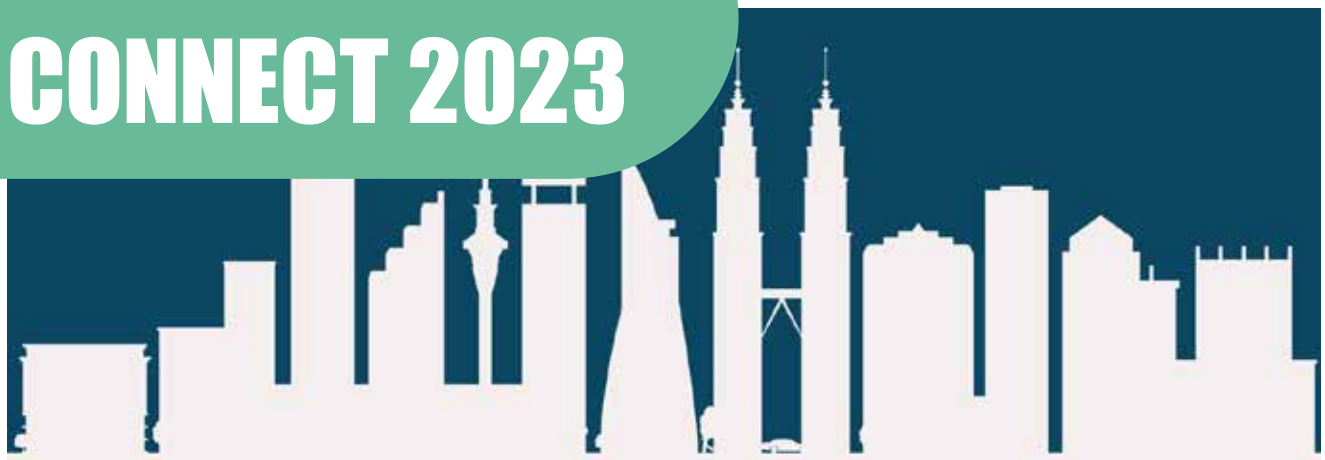
Clinical Research was first introduced to me during my family medicine postgraduate training in UKM (2013-2017) as conducting research was part of the requirement. In 2019, I got transferred to Seremban 2 Health clinic and was lucky that Dr Mastura Ismail was the head of clinic at that time. She gave me the opportunity to be apart of her research team as sub investigator, and later as Principal Investigator after she retired.

My patients are the main factor that influenced me to conduct clinical trials. In primary care, we see variety of cases and disease spectrum reflecting the total population. Besides helping others, patients get the advantage to experience newest treatment first that could possibly alleviate symptoms of their disease. They also receive personalize care and closer monitoring of their health from the clinical trial staff.

I would highly recommend all my peers especially in primary care to take up clinical research as it is through clinical research we will be kept updated with the latest medical technology and therapies. Besides, we get the opportunity to broaden our networking and get the privilege to participate in discussion with the internationally recognized experts of the field. In the end, our involvement in clinical research will not just improve our overall profession and career but it will also improve patient care.

> **"Besides helping others, patients get the advantage to experience newest treatment first that could possibly alleviate symptoms of their disease. They also receive personalize care and closer monitoring of their health from the clinical trial staff"**
>
> **Dr Noor Mikraz**

CRM TRIAL CONNECT 2023



Accelerating Malaysia in Global Clinical Trials

CRM TRIAL CONNECT 11-12 MAY 2023

InterContinental Kuala Lumpur

Program Highlights

Clinical Research Excellence: Sharing by Top Investigators & Sites | Industry & Investigator Dialogues | Global Networks of Excellence | Tapping into the Potential of Primary Healthcare and Private Centres | Patient Engagement | Insights into Clinical Trials' Design & Conduct | Innovations in Clinical Trials

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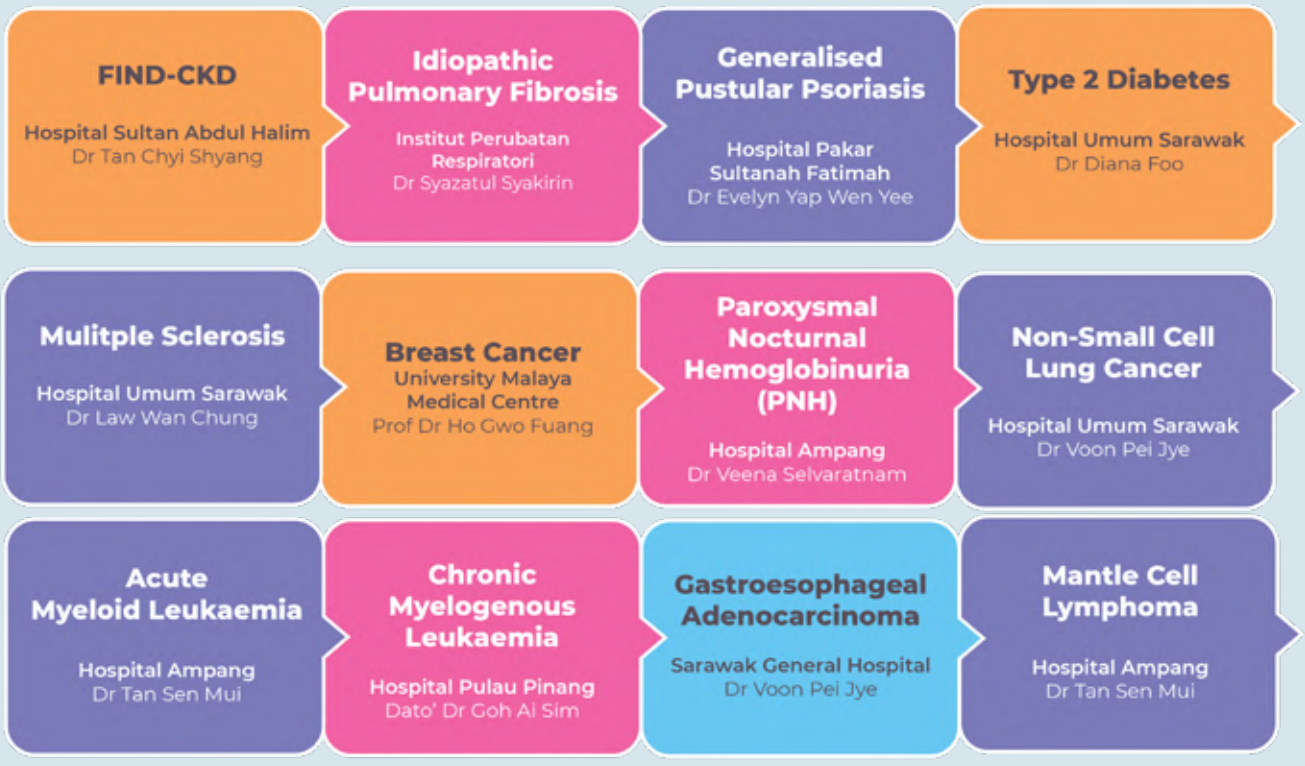
www.crmtrialconnect.com

INFOGRAPHIC

RECRUITMENT ACHIEVEMENTS IN GLOBAL SPONSORED RESEARCH 2022



Global Top Recruiter

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Do you or someone you know have MEDICAL CONDITIONS?

such as cancer, diabetes, heart disease and others

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www.clinicalresearch.my/fact

FEATURED SITE

Hospital Pakar Sultanah Fatimah Muar

Hospital Pakar Sultanah Fatimah (HPSF) is a government-funded specialist hospital located in Bandar Maharani, Muar, Johor under Ministry of Health, Malaysia. It functions as referral hospital in the northern region of Johor State for neighbouring districts such as Hospital Batu Pahat, Segamat and Tangkak.

The hospital was established in 1900 in a small building at Jalan Petri, Muar and during the early years was known as the “Government Dispensary” situated opposite the Muar Trade Centre building. The whole health service was later shifted to the current location at Jalan Salleh in 1918 when the town of Muar was being restructured.

Back in the 1920s, the hospital which was once known as the Muar District Hospital has gone through a variety of developments and transformations into a specialist hospital under the tenure of YB Dato’ Chua Jui Meng as Minister of Health (1995 – 2004), who was also a former local-bred Member of Parliament (MP) for Bakri. On 13 October 2003, the hospital status and name were converted from 'Hospital Muar' to the present 'Hospital Pakar Sultanah Fatimah' with the declaration officially completed by then Sultanah of Johor, Sultanah Zanariah

Departments, units, and services available at HPSF are as listed below:

Clinical
- Medical
- Surgical
- Paediatric
- Orthopaedic
- Obstetrics & Gynaecology
- Ophthalmology
- Otorhinolaryngology
- Anaesthesiology
- Dermatology
- Psychiatry
- Emergency & trauma
- Nephrology
- Oncology
- Physiotherapy
- Rehabilitation
- Oral
- Maxillofacial Surgery

Support
- Management
- Nursing
- Assistant Medical Officer
- Clinical Research Centre
- Library
- ICT

Clinical Diagnostic
- Diagnostic & Imaging
- Pathology
- Forensic

Clinical Support
- Tissue & Organ Procurement Team
- Pharmacy
- Health Education
- Social Media Work
- Dietetic & Food
- CSSD

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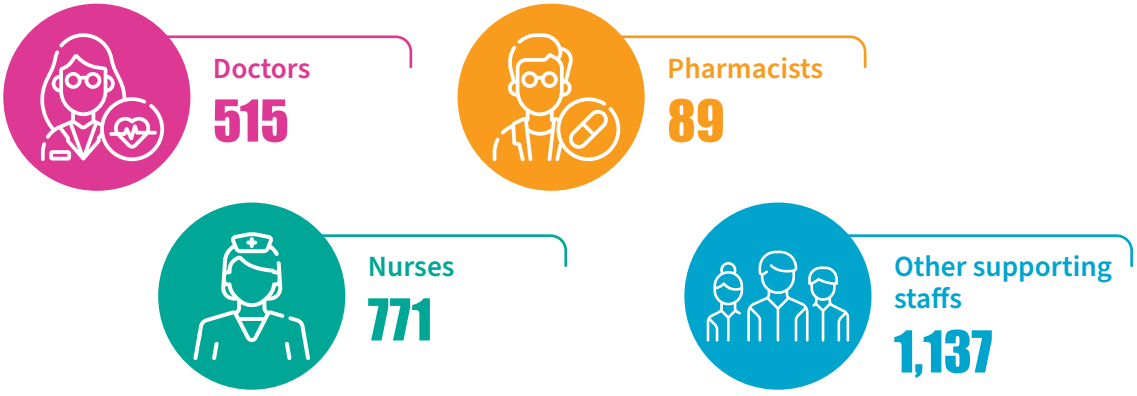
Clinic Governance
- Unit Quality
- Unit Medicolegal
- Unit Cluster
- Infection Control
- Occupational Safety & Health (OSH)
- Unit Medical Record
- Public Health
- Supervision & Transportation

Hospital Pakar Sultanah Fatimah specializes in these following therapeutic areas:

- Rheumatology
- Nephrology
- Oncology

In addition, HPSF also plays the role as teaching hospital being affiliated with medical schools i.e., Manipal University College Malaysia (formerly Melaka Manipal Medical College) and Asia Metropolitan University to provide medical education and training for medical students.

Total Workforce/ Staff in Hospital Pakar Sultanah Fatimah



Numbers of population served: 205,796

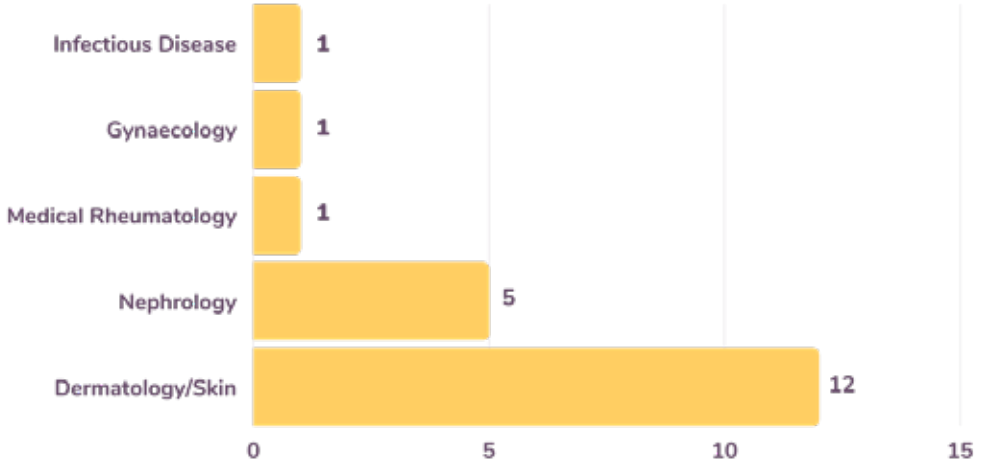
Clinical Research Centre, HPSF

Clinical Research Centre (CRC) Hospital Pakar Sultanah Fatimah, Muar was established in 2015 where it was placed under Dr. Noorizan binti Yahya, as Head of CRC. This centre was inaugurated on the 3rd of October 2019 by Dr. Selahuddeen Bin Abdul Aziz, who was the Johor State Health Director at the time. CRC is located on the 2nd floor of the HPSF cafeteria which has been renovated from a visitor lodge to a full CRC management office.

The entire centre can accommodate research in Muar and surrounding districts for study and training purposes. Its core function is to promote research activities in both Industrial Sponsored Research (ISR) and Investigator Initiated Research (IIR) and conduct research-related training. CRC in HPSF is committed to promote and support the importance, quality, safety, and efficiency of clinical research.

CRC HPSF Facilities

Numbers of sponsored studies conducted in HPSF based on therapeutic areas



Sourced from CRMx

Clinical Research Achievements

2022 - ANB019-301: First in Patient Randomized Globally - Generalized Pustular Psoriasis

BI1368.13: Dr Evelyn as Co-Author, The Journal of Dermatology 2022

PUBLICATIONS

Managing Clinical Trials Agreements

Applied Clinical Trials, Published on 13 May 2022

Authors: Siti Nuralis binti Abd Muis, Heidi Nai Soraya Roslan, Nurul Atiqah Binti Abd Rahman

How Clinical Research Malaysia sped up CTA turnaround using web-based system

A Clinical Trial Agreement (CTA) as defined in The Malaysian Guideline for Good Clinical Practice is "a written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract."[1]

Review and negotiation of a CTA is an important process as it affects the trial activities conducted at site since the study or trial could not commence without any CTA in place. In 2015, the Clinical Research Malaysia (CRM) Legal & Regulatory Affairs Department developed its Clinical Trial Agreement System (CTA System) to provide a systematic and efficient way to review, as well as speed up the CTA process. This CTA System is an online platform where all the CTA(s) for the Malaysian Ministry of Health sites are submitted by sponsors and CROs.

The CTA System was launched in March 2016 and since then, all the negotiation, review, approval, and endorsement of the CTA are conducted via the CTA System, which features automatic alerts to CRM Legal to review. The total number of CTAs that have been reviewed via CTA System is illustrated below featuring a total of 562. Currently, there are 180 sponsors, 49 CROs who are registered under the CTA system, who are in charge of negotiating the CTA terms and conditions, as well as the study budget with the site.

Year	No. of initiated CTAs
2016	77
2017	86
2018	78
2019	101
2020	81
2021	104
March 2022	35

System Benefits

Sponsors and CROs can keep track of CTA status from the day of study registration until completion. The system offers transparency of the collaboration of work between the sponsor/CROs and CRM's Legal & Finance department as all the correspondences and communication are held within the system.

The CTA System enables the CRM Legal & Regulatory Affairs department to keep track of studies by accessing 'New' & 'Review' tabs for the studies which are still in the reviewing process, and the 'Settled' tab for the studies which have been endorsed by the reviewer. Registered users can also transfer and handover a specific study from a previously registered clinical research assistant to the new appointed clinical research assistant, which provides a seamless flow of information. This assignment and changes of the study is still subject to the approval of the registered user of the study in the CTA System. Another alert feature prompts a notification via-email when a user has given a comment in the platform, allowing all parties to be aware of changes or a need to act. Prior to the system's implementation, from 2012 to 2015, the CRM Legal & Regulatory Affairs department took an average of 59 days to review CTA until endorsement.[2] Since the system's implementation, CTA review has been expedited only 14 days.

Data Management Security

When there are any activities that involve data interchange, secure data management should be a top priority. With CTA System authentication and encryption methods, a secure data management protects parties involved in the CTA negotiation from data losses, thefts, and breaches. Strong data security ensures that critical CRM and clinical research assistant data is backed up daily and retrievable in the event that the primary source fails. The CTA system provides a safe, centralized site for data collection and storage, as the clinical research assistant provides some confidential data in the CTA system for the purpose of CTA review, such as the study protocol, study budget, and so on.

References

1. National Pharmaceutical Regulatory Agency (NPRA) Ministry of Health Malaysia. Malaysian Guideline for Good Clinical Practice (Fourth Edition). Glossary 1.21. pg 10. 2018.

2. https://clinicalresearch.my/evolution-of-clinical-trial-agreement/

Managing Clinical Trials in Malaysia: Current and Future Perspective (Excerpt Edition)

Asia Pacific Journal of Clinical Oncology, Published on 28 October 2022

Authors: Pei-Jye Voon, Wei-Hong Lai, Ros Suzanna Bustaman, Lillian L. Siu, Albiruni R. Abdul Razak, Akhmal Yusof, Noor Hisham Abdullah

Abstract

Historically, the majority of oncology clinical trials are conducted in Western Europe and North America. Globalization of drug development has resulted in sponsors shifting their focus to the Asia Pacific region. In Malaysia, implementation of various government policies to promote clinical trials has been initiated over a decade ago and includes the establishment of Clinical Research Malaysia (CRM), which functions as a facilitator and enabler of industry-sponsored clinical trials on a nationwide basis. Although oncology clinical trials in Malaysia have seen promising growth, there is still only a limited number of early phase oncology studies being conducted. Hence, the Phase 1 Realization Project (P1RP) was initiated to develop Malaysia's early phase clinical trial capabilities. In addition, the adaptation of good practices from other countries contribute to the effective implementation of existing initiatives to drive progress in the development of early phase drug development set up in Malaysia. Furthermore, holistic approaches with emphasis in training and education, infrastructure capacities, strategic alliances, reinforcement of upstream activities in the value chain of drug development, enhance patient advocacy, coupled with continued commitment from policy makers are imperative in nurturing a resilient clinical research ecosystem in the country.

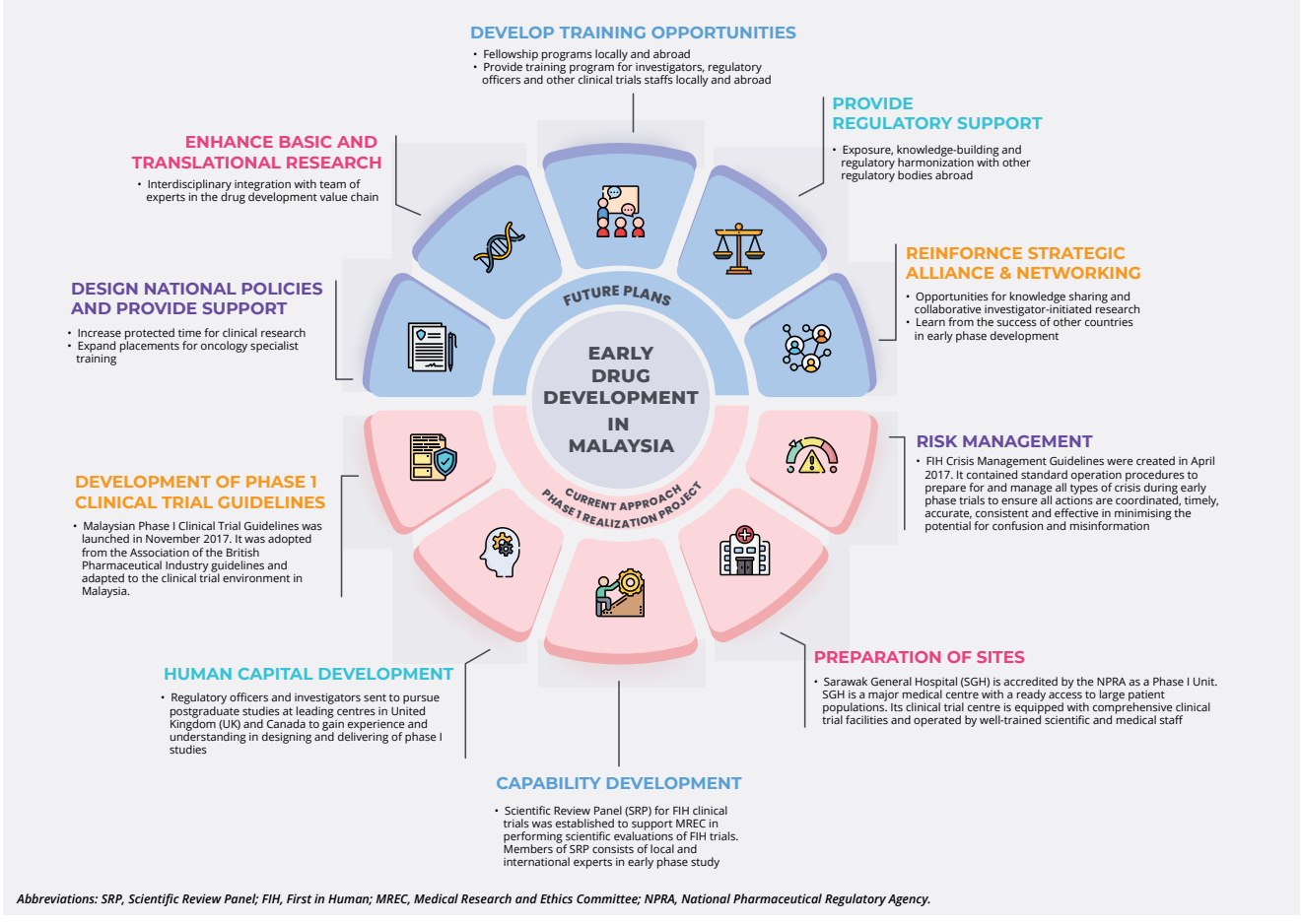


Figure : Early Drug Development in Malaysia: Current initiatives and future perspectives

Table: Five pillars of phase 1 realization project (P1RP)

Pillar	Measures
Development of phase 1 clinical trial guidelines	• Malaysian Phase 1 Clinical Trial Guidelines was launched in November 2017 • Based on ABPI 2012 version of phase 1 clinical trial guidelines • Local regulatory bodies and agencies' existing procedures, and the local clinical trial environment were considered to facilitate the applicability of the ABPI guidelines in the country
Human Capital Development	• Regulatory officers and investigators were sent to pursue their postgraduate studies to leading centers in United Kingdom and Canada to gain experience and understanding in designing and delivering of phase I studies
Capability Development	• SRP for FIH clinical trials was established to support the MREC, a centralized ethics committee, in performing scientific evaluations of FIH trials conducted in clinical trial sites in Malaysia • Members of SRP consist of local and international experts in early phase study as well as clinical pharmacologists who have experience in evaluating FIH studies
Preparation of Sites	• Sarawak General Hospital is accredited by the NPRA as a Phase I Unit. This hospital is a major medical center with a ready access to large patient populations, and its clinical trial center is equipped with comprehensive clinical trial facilities encompassing intensive and high dependency research unit, dedicated research laboratory, and correlative studies facilities, and it is also operated by well-trained scientific and medical staffs
Risk Management	• FIH crises management guidelines were created in April 2017. It contained SOP to prepare for and manage all types of crises requiring immediate attention during early phase trials to ensure all actions are coordinated, timely, accurate, consistent and effective in minimizing the potential for confusion and misinformation

Conclusion

Malaysia is one of the emerging clinical trial sites, and this was achieved due to various government efforts such as the establishment of CRM nd the P1RP initiative. To date, although it has accomplished tremen- dous progress in the conduct of pivotal or late phase clinical trials, there is a need to sow and provide fertile ground for the growth of early phase trials. The successful conduct and delivery of early phase trials may raise the confidence of trial sponsors, which will result in a spillover effect of more phase II and III studies into the country. This is especially crucial in the current era whereby there is an emergence of different innovative trial designs in drug development; and one of the examples is "phase agnostic seamless drug development," which is deemed to be more efficient than the conventional clinical designs with better utilization of resources and reducing the time it takes to complete the process of drug development.[45] This has underscored the urgent need of Malaysia in building a robust clinical trial ecosystem encompassing early phase through to late phase drug development as the boundary of "phases" of oncology studies has increasingly blurred, and the country will certainly be left behind if it is still focusing on late phase drug development.

Vigorous partnerships between academic research center and can- cer service providers, efficient networking with the regional peers and industries as well as strong commitment and continuous investment from the Malaysian government are imperative in building a sustain- able and conducive ecosystem for oncology research in the country. Ultimately, building and nurturing a robust clinical research ecosys- tem is dependent on the understanding of cancer biology and applying experimental therapeutics with an eventual goal to provide high quality cancer care to patients.

Link to full text article is available at: https://clinicalresearch.my/articles/

"The successful conduct and delivery of early phase trials may raise the confidence of trial sponsors, which will result in a spillover effect of more phase II and III studies into the country"

CRM IN PHOTOS

Visit by Universiti Putra Malaysia Teaching Hospital

1 Aug

Meeting with Dr Albiruni Razak, Princess Margaret Cancer Centre, Canada

9 Aug

Mount Kinabalu Expedition by CRM Sports & Recreational Club

12 Aug

Meeting with Mr Miyasaka Tomuki (Health Labor Welfare Attache, Embassy of Japan)

19 Aug

Visit to Columbia Asia Bukit Rimau Hospital

21 Aug

Meeting with Mejar General Dato Dr Rosman, Hospital Angkatan Tentera Tuanku Mizan

9 Sep

Meeting with Tigermed

4 Oct

Launch of CRM Trial Connect 2022, by YBMK Khairy Jamaluddin

18 Oct

Meeting with Dr Wendy Tay, Country Medical Director at Roche

20 Oct

Visit to National Cancer Society Malaysia

1 Nov

Meeting with Pantai Premier Group

2 Nov

Meeting with IBX Protech

4 Nov

CRM IN PHOTOS

Meeting with Merck Sharp & Dohme

11 Nov

Meeting with Fujian Cosunter Pharmaceutical

14 Nov

Meeting with Marken

16 Nov

Visit to Malaysian Genomic Resource Centre

21 Nov

Meeting with ICON

24 Nov

Meeting with Ungku Shahrin Medical Aesthetic Research & Innovation (USMARI) Centre

24 Nov

Meeting with Prof Patrick of Swinburne University of Technology Sarawak Campus

25 Nov

CRM's visit to Institut Kanser Negara

9 Dec

CRM 's visit to Hospital Tengku Ampuan Afzan

15 Dec

Meeting with Pharmaceutical Association of Malaysia

16 Dec

Appreciation farewell to YB Khairy Jamaluddin

19 Dec

Farewell to Mr Miyasaka Tomuki, (Health Labor Welfare Attache, Embassy of Japan)

19 Dec

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CRM
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