BY CLINICAL RESEARCH MALAYSIA

CRM Bulletin

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PUSHING BOUNDARIES, DELIVERING LIFE-CHANGING THERAPEUTICS

RESEARCH PERSONALITY

Dr Fariz Safhan

RISING STARS IN ONCOLOGY

FEATURED SITE

Hospital Sultanah Nur Zahirah

About Clinical Research Malaysia

Clinical Research Malaysia (CRM) is a Global Trusted Research Management Organisation established by the Ministry of Health Malaysia in 2012. The organisation is guided by the principles of Humanity, Stability and Sustainability in providing global clinical trial solutions and enabling a thriving clinical research ecosystem in the country. At its very core, CRM aims to bring clinical research that addresses the unmet needs of patients and transforms health outcomes in Malaysia.

CRM delivers sponsored clinical trials with Speed, Reliability and Quality through operational excellence and working with stakeholders by providing end-to-end clinical research support services. Certified with both ISO 9001:2015 (Quality Management System) and ISO 37001:2016 (Anti-Bribery Management System), and being aligned to international regulations, our core values and code of conduct are ingrained throughout CRM. The strength of this organisation lies in the people of CRM as we strive in our vision to make Malaysia the preferred clinical research hub in Asia.

CRM
CLINICAL RESEARCH MALAYSIA
Your Global Solutions in One Nation

From The CEO's Desk

Warmest welcome to CRM Bulletin Issue 25!

The year 2022 stands as a pivotal chapter in our story, marked by a series of accomplishments that have made an enduring mark on the realm of clinical research. A decade of steadfast dedication culminated in the joyous commemoration of our 10th anniversary, where we shared stories of triumph that underscored our commitment to innovation. Among these achievements, the inception of the 1st CRM Trial Connect stands tall, exemplifying our forward-thinking approach and our prowess in fostering transformative collaborations. Equally noteworthy was the landmark accomplishment of reaching RM 1 Billion in Clinical Trial Agreements, a testament to our unwavering pursuit of excellence.

As we look ahead, the horizon holds even grander prospects. Our meticulously planned short-term vision, extending until 2026, has garnered unwavering support from our esteemed Board of Directors led by our chairperson, Minister of Health. I hold the sincere hope that every member of CRM will contribute their expertise and dedication to the realization of this vision, akin to the resounding success we achieved in the establishment of CRM objectives.

Our journey into 2023 began with a significant stride as we forged the UK-Malaysia Clinical Research Partnership. This visionary collaboration aimed to unite the brightest minds in Malaysian clinical research with their counterparts in the United Kingdom, exploring synergistic avenues for research in alignment with the Ministry of Health Malaysia.

The initial half of this year bore witness to our active involvement in global conferences, expanding our horizons and solidifying our network within the realm of clinical research. Particularly noteworthy was our debut appearance at DIA China 2023, where CRM had the privilege of being invited by Tigermed to speak and promote Malaysia as a hub for clinical research in the ASEAN region. These international engagements stand as a testament to our steadfast commitment to elevating Malaysia as a paramount hub for clinical research on the global stage.

A pinnacle in our annual calendar was the 2nd CRM Trial Connect Conference, seamlessly following the resounding success of its predecessor. Combined with the celebration of Clinical Trials Day and the presentation of Sponsored Research Awards, this event vividly demonstrated the enthusiasm of our community. The participation of 530 delegates from 105 organizations spanning 12 countries, along with 14 exhibitors, eloquently affirmed the resonance of our collective purpose.

In conclusion, I encapsulate our ethos with the words: Humanity, Stability, and Sustainability. As the bedrock of our mission, we stand as the embodiment of a Global Trusted Management Organization, unwavering in our commitment to Core Values and Code of Conduct. Our determination to execute Key Strategies with Operational Excellence remains our guiding light.

As each year passes, the crescendo of our journey gains resonance. Standing on the brink of 2023, I extend heartfelt gratitude for your unwavering dedication and unyielding spirit. With immense pride, I reaffirm our collective pledge to realize the Vision 2026. United, there is no summit beyond our reach.

Dr. Akhmal Yusof
CEO, Clinical Research Malaysia

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CRM GUIDING PRINCIPLES

CRM CLINICAL TRIAL ADVERTISEMENT SERVICES

Platform

- Facebook & Instagram
- Targeted audience approached via Sponsored Ads

contact: bd@clinicalresearch.my

CRM STUDY MATERIAL 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

UK-Malaysia Clinical Research Partnership

30 January 2023 – CRM's UK-Malaysia Clinical Research Partnership forum drew a packed crowd with 100+ UK researchers. CRM's first-of-its-kind event sparked active cross-country research interest with Malaysian panelists from esteemed UK institutions discussing on the clinical research developments observed from Malaysia.

The Academy of Medical Sciences, UK

31 January 2023 – In addition to the forum held, CRM also met with the Academy of Medical Sciences in UK, led by Simon Denegri, Executive Director. Both organisations exchanged information on respective roles and function in addition to exploring capability development and knowledge sharing that will positively impact global research and health.

First ARISE Annual Meeting

8 February 2023 – Clinical Research Malaysia's CEO, Dr Akhmal Yusof delivered an impactful session on CRM's initiatives in encouraging & supporting clinicians journey in becoming Clinical Researchers. With Malaysia having over 1000 investigators from various speciality, CRM works with study sites in enabling the development of research investigators.

Nurturing New Talents in Sponsored Research

23 February & 19 May 2023 – CRM held two Nurturing New Talents in Sponsored Research, one of it being co-organised with Pantai Hospital Kuala Lumpur. In addition, CRM also participated in an ISR workshop organised by Hospital Tengku Ampuan Rahimah on 7 March with the same aim in encouraging clinicians to initiate their investigator journey. Special thanks to our investigators and CRM representatives for the insightful session and experience sharing.

Decentralised Clinical Trial (DCT) Guidance Document Workshop

22 March 2023 – The Decentralised Clinical Trial (DCT) Working Group members convened to develop Malaysia's first DCT guidance document. The members consist of representatives from ethics committees, regulators, home health service provider, site study team and sponsors/CROs.

Patient Recruitment & Retention Workshops

21 March & 16 May 2023 - CRM's Clinical Operations team have successfully conducted its two Patient Recruitment & Retention workshops in the first half of 2023 with attendees from internal and external stakeholders. Our hope is that the method and strategies shared will be benefited to the attendees.

Preparation for Regulatory Inspection Workshop

12 April 2023 – Kudos to CRM for successfully conducting its 1st Preparation for Regulatory Inspection workshop for year 2023. Special thanks to the speakers who delivered an insightful session towards the investigators and research teams during the workshop.

American Society for Clinical Oncology (ASCO) Annual Meeting 2023

6 June 2023 - CRM was thrilled to participate in ASCO 2023 for the second time running. The program which host a wide array of topics, provided excellent exposure on early phase data on emerging novel therapies.

DIA China 2023

16 - 19 June 2023 - A first for CRM to attend and speak at DIA China 2023 to share Malaysia's clinical research landscape and to attract more sponsored research to the country and to the SEA region. Thank you Tigermed for the invitation to speak at its forum.

DIA 2023 Global Annual Meeting

27 June 2023- CRM was at the DIA 2023 Global Annual Meeting, and we were glad to connect with sponsors, CROs, regulators, and clinical research service providers from all over the world. Progressive developments in the fields of AI and DCT were among key learnings from this meet.

SPOTLIGHT FEATURE

CRM Trial Connect 2023

In a bid to further enhance its position as a global player in clinical research, Clinical Research Malaysia organized a remarkable conference that surpassed the success of its inaugural international clinical trial networking event held the previous year. The two-day event, held in conjunction with International Clinical Trials Day, brought together distinguished guests, presenters, speakers, and delegates from various sectors of the clinical research community.

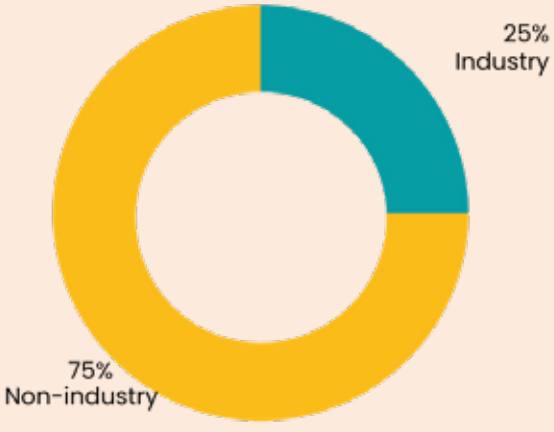
The opening ceremony were officiated by Health Minister, YB Dr Zaliha Mustafa. Notably the ceremony also served as a platform to commemorate International Clinical Trials Day which honored the dedicated investigators, clinical trial site staff, sponsors, Contract Research Organization partners, and patients. Their unwavering commitment to conducting timely, safe, and high-quality studies was recognized, as they bridge the gaps in unmet treatment and diagnostic needs, offering hope in patients. The conference also included Sponsored Research Awards ceremony to acknowledge and celebrate the top achievers in clinical research such as Top Recruiter, Investigator of the Year, Top Study Site and Sponsor of the Year.

The conference featured a forum on cultivating optimal environments for clinical research, where esteemed speakers from public, university, and private sectors, including Datuk Dr Muhammad Radzi Hassan (Director General of Health) & Datuk Dr Nor Fariza Ngah (Deputy Director General in Research & Technical Support) shared valuable perspectives on creating optimal environments for conducting clinical trials. Lessons on site development were provided by experienced clinical trialists, Dr. Voon Pei Jye, Prof. Dr. Nazirah Hasnan, and Dr. Alan Fong Yean Yip. Insights into excelling in patient recruitment were shared by Dr. Sharon Ng Shi Min from Hospital Ampang. The potential of primary healthcare and private centers in sponsored research was explored by Dr. V Paranthaman, Dr. Norsiah Ali, Dr. Ng Soo Chin, and Dr. Wong Shin Yee.

The conference also highlighted innovations and emerging trends in clinical trials, including decentralized trials and real-world data, through presentations by representatives from IQVIA, Janssen, and Novartis. Global site practices were emphasized, with esteemed speakers from abroad, including Dr. Jennifer Croke, Prof. Goh Boon Cher, Dr. Aaron Hansen, and Dr. Ezanul Abd Wahab, contributing to the knowledge exchange and the growth of the Malaysian clinical trial environment.

Uptake and public engagement in clinical trials conducted within the country were discussed extensively, along with a panel discussion involving clinical trial volunteers and former Health Minister, Mr. Khairy Jamaluddin, who shared valuable insights based on their experiences. Recognizing the importance of regular discourse between key government agencies and the industry, the conference facilitated an industry forum that brought medical device players together with the National Pharmaceutical Regulatory Agency, Medical Research and Ethics Committee and the Medical Device Authority. The aim was to foster better understanding and addressing opportunities excellence in clinical research.

The conference concluded on a high note, with CRM commended for yet another successful international event. CRM Trial Connect 2023 showcased Malaysia's capabilities, experience, and achievements in multinational clinical research. The presentations, discussions, and knowledge sharing throughout the two days left a lasting impact on participants, further motivating them to excel in clinical trial conduct. The event served as a platform for delegates to connect, learn, and contribute to the advancement of clinical trials in Malaysia.



Sponsored Research Awards

CRM Sponsored Research Awards (SRA) was presented by Minister of Health, YB Dr Zaliha to outstanding achievers in sponsored clinical research in the country during CRM Trial Connect Conference on 11th May 2023. Among investigators who received the awards include Dr Voon Pei Jye (Oncologist) from Sarawak General Hospital and Dr Sharon Ng (Physician) from Ampang Hospital who were the recipient of Top Investigator and Top Recruiter awards, respectively.

Dr. Lily Wong Lee Lee was honoured with the Significant Advancement Award for Investigator. Her remarkable accomplishment showcased a substantial increase in sponsored studies in 2022 compared to previous years. Similarly, the Significant Advancement Award for Site was bestowed upon Queen Elizabeth Hospital, which demonstrated significant growth in sponsored studies with the inclusion of 16 new studies at their site.

Sarawak General Hospital and University Malaya Medical Centre were both recognized as Top Study Site for conducting high numbers of sponsored studies in 2022. Meanwhile, Novartis received ‘Sponsor of the Year’ for bringing in the highest number of trials, while IQVIA Malaysia received 'CRO of the Year’ award for contracting the highest number of new clinical trials last year.

INVESTIGATOR OF THE YEAR
DR VOON PEI JYE
SARAWAK GENERAL HOSPITAL

TOP RECRUITER
DR SHARON NG SHI MIN
AMPANG HOSPITAL

SIGNIFICANT ADVANCEMENT AWARD FOR INVESTIGATOR
DR LILY WONG LEE LEE
QUEEN ELIZABETH HOSPITAL

TOP STUDY SITE (MOH)
SARAWAK GENERAL HOSPITAL

TOP STUDY SITE (OVERALL)
UNIVERSITY MALAYA MEDICAL CENTRE

SIGNIFICANT ADVANCEMENT AWARD FOR SITE
QUEEN ELIZABETH HOSPITAL

SPONSOR OF THE YEAR
NOVARTIS

CRO OF THE YEAR
IQVIA RDS SDN BHD

IN THE NEWS

Achievements In Sponsored Clinical Research Places Malaysia At The Forefront Of Global Multinational Clinical Trials

PUTRAJAYA, 3 April 2023 – AstraZeneca Sdn Bhd, a leading global biopharmaceutical company, formalized their collaboration with Clinical Research Malaysia (CRM) and Sarawak General Hospital (SGH) through the signing of a Memorandum of Understanding (MoU). The MoU signing took place after the launch of the CRM Annual Report and solidifies SGH's role as a focused site for conducting more international clinical trials, including early phase studies sponsored by AstraZeneca.

This collaboration builds upon SGH's accreditation in 2019 as a Phase 1 site, achieved through the successful completion of the National Pharmaceutical Regulatory Agency Phase 1 Unit Inspection & Accreditation Programme. The MoU signifies an opportunity to provide early access to innovative medicines for patients with unmet medical needs, thereby improving health outcomes and reducing the national disease burden. The agreement outlines the commitment of both parties to work together in delivering high-quality studies that meet international standards, supporting training for investigators and study teams, and creating additional clinical trial opportunities at SGH.

The signing ceremony took place at the Ministry of Health office in Putrajaya and involved Ms. Pneh Tee Koon, Cluster Chief Financial Officer representing AstraZeneca, and Dr. Akhmal Yusof, CEO of CRM. The event was witnessed by Dr. Zaliha Mustafa, Minister of Health, and Dr. Sanjeev Panchal, Company Director of AstraZeneca Malaysia.

KUALA LUMPUR, 11 May 2023 – Clinical Research Malaysia (CRM) renewed its partnership with IQVIA, a leading global provider of advanced analytics, technology solutions and clinical research services to the life sciences industry, at the CRM Trial Connect 2023 conference held at Intercontinental Kuala Lumpur.

The program, which was established in 2013 and involved CRM and the Institute for Clinical Research (ICR), has yielded exceptional results. Notable achievements include a substantial increase in IQVIA's trial patient enrolment, reduction in contract timelines, high protocol compliance, and improved performance at trial sites. In addition, the high-performing network received recognition from IQVIA earlier this year for its exemplary performance. The renewal of the partnership was witnessed by YB Dr. Zaliha Mustafa, Minister of Health, and Mr. Ben Laverty, Head of R&D Operations (Southeast Asia, Australia, and New Zealand).

In line with Malaysia's initiatives to expand into decentralized clinical trials, CRM has formalized its partnership with Marken, a leading end-to-end solution provider for clinical research. This strategic collaboration aims to enhance Malaysia's capabilities in home health care services, a crucial aspect of decentralized trials. Marken's expertise and comprehensive solutions will play a vital role in supporting the country's efforts to conduct clinical trials in more patient-centric settings.

The renewal of CRM's partnership with IQVIA and the formalization of its partnership with Marken mark significant milestones in Malaysia's clinical research landscape. These collaborations demonstrate the country's commitment to fostering innovation and improving healthcare outcomes through robust clinical trials. By strengthening relationships with industry leaders like IQVIA and Marken, CRM is well-positioned to drive advancements in clinical research and provide valuable opportunities for patients and researchers alike.

RESEARCH PERSONALITY

Dr Fariz Safhan

Consultant Nephrologist & Physician,
Head of Nephrology Services Pahang,
Head of Nephrology Department &
Head of Clinical Research Centre, Hospital Tengku Ampuan Afzan

About Dr Fariz Safhan

Dr. Fariz Safhan completed his medical degree from the University of Otago, New Zealand, in 1999 and started practicing medicine since 2000. He obtained his Masters in Medicine (Internal Medicine) from Universiti Sains Malaysia in 2008 and completed his fellowship sub-specialty training in Nephrology under the Ministry of Health (MOH) Malaysia in 2013. Currently, Dr. Fariz serves as the Pahang State Nephrologist, primarily based at HTAA, Kuantan. He also provides nephrology services at various MOH Hospitals in Pahang and conducts nephrology clinics at KPJ Pahang and consultation clinics at different private/ NGO hemodialysis centers. Additionally, he holds the positions of Honorary Lecturer at UIAM Medical School and auditor for the Malaysian Society of Quality Health (MSQH) in Haemodialysis Services.

Dr. Fariz actively engages in clinical research and has numerous publications in various journals in addition to oral and poster presentations. Throughout his career, he was involved in over 70 research studies, including 26 clinical trials. He was the principal investigator in 15 trials and the national lead coordinating or corresponding principal investigator in 6 trials. His research interest is focused on nephrology, specifically in IgA Nephropathy, Chronic Kidney Disease, Lupus Nephritis, Critical Care Nephrology, and End Stage Kidney Disease. Dr. Fariz has received recognitions for his contributions to clinical research, including being named top recruiter for IgA Nephropathy and Lupus Nephritis research within APAC region and globally. He is also an active speaker at conferences and courses related to nephrology and internal medicine, participating at the state, national, and international levels.

Share with us your initial journey in clinical research

I have always been deeply interested in research since the early days of my career. It all started during my Masters in Internal Medicine, where I focused on my thesis and conducted few investigator-initiated research (IIR). As a junior specialist, I began participating in global clinical trials as a sub-investigator, specifically in the fields of diabetes, hepatology, and cardiology and had the privilege of collaborating with esteemed senior investigators such as Prof Dato' Dr Mohd Basri, Prof How Soon Hin, Dr Tee Hoi Poh, Prof Nik Nurfatnoon, Dr Ng Kok Huan and Dr Jannatul Ain. I was truly inspired by their commitment and dedication towards clinical research.

Upon becoming a nephrologist, I gained recognition and was invited by study sponsors, Clinical Research Organizations (CROs), and Clinical Research Malaysia (CRM) to serve as the principal investigator in global nephrology clinical trials. My earlier experiences thoroughly prepared me to take on the challenges and responsibilities as a site Principal Investigator for global clinical research trials, and later as a National Lead Coordinating/ Corresponding Principal Investigator.

As our research work gained more recognition, we received increased opportunities for clinical research. This was evident through the increased feasibility assessments and requests. Study administrators and study coordinators from CRM played a vital role in facilitating the inclusion of more studies and providing assistance during trial conduct. These circumstances further opened doors for me to pursue my research interests in nephrology. I maintained a keen focus on impactful investigator-initiated research, resulting in several journal publications, particularly in the field of nephrology.

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

Yes, very much so. Participation in clinical trials has changed our practice considerably as we have the opportunity to engage the patients with additional new and potentially ground-breaking treatments that may offer a cure or better disease control. In nephrology, various clinical conditions such as IgA Nephropathy, Lupus Nephritis, and Membranous Nephropathy have limited treatment options with minimal side effects. Our primary goal in treating these conditions is in achieving disease remission and preventing the progression to Chronic Kidney Disease (CKD). While CKD is irreversible, we can slow down its progression and enhance control to prevent or delay the development of End Stage Kidney Disease (ESKD). For patients who reach ESKD, our aim is to provide effective Renal Replacement Therapy (Transplant or Dialysis) and minimize complications to ensure a good quality of life.

Research plays a vital role in overcoming these challenges and advancing medical practices to improve patient outcomes. When selecting patients for clinical trials, study team carefully consider those with specific conditions mentioned earlier and discuss the potential benefits and risks of participation. Patients are informed and aware that they may be receiving placebo treatment, but most studies offer open label extension with studied medications after the initial periods of placebo controlled treatment. This is one of the main reasons why I have been involved in many clinical trials on these conditions such as IgA Nephropathy and Lupus Nephritis. Furthermore, many new drugs which started off being evaluated in trials are now the mainstay of treatment in some of these conditions. I thus use my research work to aid the management of my clinical patients, with the aim of giving them better treatment with less complications, as well as improving their quality of life.

In general, I would like to see a lot of efforts being done to prevent CKD. In addition, it would be desirable if our national renal transplant rate could be improved in view of our high numbers of CKD and ESKD patients. The Malaysian public, especially those with risk factors for CKD, must also play their part in taking better care of their health to help to reduce these numbers.

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

I often face time and manpower limitations, which require me to handle multiple responsibilities concurrently, including clinical, administrative, and research tasks. Additionally, the COVID-19 pandemic has presented significant challenges. Recruiting eligible patients for certain studies can be particularly challenging. However, I firmly believe that motivation, teamwork, and commitment are essential in overcoming these obstacles.

Effective multitasking and proper time management is a must. I was fortunate to be able to do this together with my excellent research team. These include the sub-investigators (nephrologists colleagues) Dr Mohd Kamil Ahmad, Dr Wan Ahmad Syahril Wan Ahmad Rozli, Dr Ng Tze Jian and Dr Chan Chee Eng, as well as the designated specialists, renal nurses and renal pharmacists. The Study Coordinators from Clinical Research Malaysia (CRM) and Clinical Research Centre (CRC) HTAA have been immensely helpful in assisting with clinical trials, in particular Mrs ‘Izzah ‘Atira, Mrs Nur Liyana and Mrs Fatihah. The support from my Hospital Director and administrative team have also been important.

I hope that my sub-investigators are inspired in their current role and go on to become principal investigators, both site and national lead in the future. The level of interest and commitment to research may vary, however many nephrologists do share a common passion for research and are motivated by the desire to benefit their patients and contribute to future advancements in the field. This dedication is driven by selfless reason rather than personal gain.

What drives and motivates you to conduct clinical trials?

As a clinician who sees many patients every day with chronic or difficult to manage conditions, I am always motivated to find more effective forms of treatment or better outcomes for them. This is what makes my role as a clinical researcher satisfying, where I can use the information obtained from the trials to improve the management of these patients and their conditions. In addition, it motivates me to contribute to scientific and medical advances and believe in pushing the frontiers of clinical science and knowledge upfront.

Clinical research is the essence of medical progress. Participating in clinical research keeps us up to date with latest medical advances, helps us become better clinicians, and provides the opportunity to become key opinion leaders and publish our research findings in journals. All this will help to enhance Malaysia as an excellent research and healthcare travel hub.

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

I would have to say motivation and patience. I have been a doctor for 23 years, a physician for 15 years and a nephrologist for 10 years predominantly in government service with some additional private work. As I have mentioned above, multitasking between clinical works, administrative duties and research activities can be challenging.

Motivation and patience, added by excellent teamwork, makes it all possible. In addition, in many of the clinical trials I have been involved, the treatments or management methods being evaluated have demonstrated a statistically significant positive outcome. However to get these treatments or new methods approved for my regular patients would take a long time. This is quite understandable, as further studies may be required to see if these findings can be replicated in different circumstances, in addition to having thorough analysis of the data by our clinical guidelines committees. All this makes it extremely satisfying on the occasions where our research team's years of hard work have resulted in the new drugs or methods studied finally being put into daily practice with our patients.

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

It is my sincere hope that more of the younger generation of clinicians will aspire to conduct clinical research and become excellent research investigators. Involvement in clinical research should be one of the main criteria for career advancement or promotion, along with more protected time allocated for research.
It would also be good to see more clinicians from a greater variety of fields participating in clinical research as well as more research centres being established in Malaysia. In addition, we need to develop more well-equipped research centres handling Phase 1 or First in Human (FIH) Clinical Trials modelled on the excellent Clinical Research Centre in Sarawak General Hospital.

More cooperation or engagement with renowned research institutions and countries are also important. CRM has played an active role in spearheading global engagement with various research institutes including South-South collaboration driven along with DNDi, the ongoing partnership with Japan institutes such as National Cancer Centre Japan and the recent engagement in UK with Malaysian researchers based in renowned institutions such as Oxford University. Research centres in hospitals should engage with CROs to be identified as preferred sites, enabling more research opportunities to be brought in. In the long term, I would also like to see Malaysia recognised as one of the main or key research hubs, both regionally and globally.

Dr Fariz Safhan in his office

Sitting (L-R): Dr Fariz Safhan, Dr Mohd Kamil, Dr Wan Ahmad Syahril Rozli
Standing (L-R): Nur Faqihah, Nur Liyana, 'Izzah 'Atira, Noryana

RISING STARS IN ONCOLOGY

Since 2012, the field of oncology has witnessed a remarkable upswing in clinical research within the Malaysian healthcare landscape. With over 330 clinical trials conducted in oncology inclusive of gynae-onco at MOH (Ministry of Health) sites, the statistics reveal a substantial surge in the pursuit of medical advancements. This surge signifies the growing interest and commitment of healthcare professionals and researchers in pushing the boundaries of cancer treatment and care.

Dr Yong Chee Meng
Consultant Gynaecological Oncologist & Gynaecological Oncological Surgeon

Hospital Ampang

Research in Gynae Oncology is essential to address gaps in patients care. With research, our aim is to move forward towards new modalities of treatments for our gynae oncology patients.

Conducting clinical trials provide me opportunities to be exposed to the latest treatments or technologies in Gynae Oncology that helps my patients gain access to the latest treatment modalities.

Clinical trials offer best way to see and move forward towards new treatment modalities for our patients in our region and I am glad to have opportunities to use new or latest medications or modalities in the treatment of Gynae Oncology in our patients in Malaysia, which otherwise, our patients would not be able to afford or have access to.

Dr Nik Ahmad Nik Abdullah
Consultant Gynaecological

Hospital Raja Perempuan Zainab II, Kelantan

Curiosity provides the "why" for the work. Curiosity provides the personal energy necessary to pursue the interest. My interest in Gynecology Oncology is not only to treat the patients but to look new method and new treatment for the patients. This can only be done by doing research.

Clinical trials are research studies that test a medical, surgical, or behavioral intervention in people. These trials are the primary way for us to determine if a new form of treatment or prevention, such as a new drug, diet, or medical device is safe and effective in people. Clinical trials and studies has changed the way I treat the patients based on the progress of evidence-based medicine. The highest level of evidence allows improvements in the way we manage patient care.

Working in clinical research gives me a unique opportunity to make a real difference to people's lives. Working towards not only saving lives but improving the quality of life for people across the globe makes a career in this field extremely rewarding.

> **"Working in clinical reseach gives me a unique opportunity to make a real difference to people's lives. Working towards not only saving lives but improving the quality of life for people across the globe makes a career in this field extremely rewarding."**
>
> **Dr Nik Ahmad**

Dr Chalaya Kumutha
Clinical Oncologist

Hospital Sultan Ismail, Johor Bharu

I am deeply passionate about and dedicated to conducting research in the fields of lung, breast, colorectal, and head & neck cancers.

The treatment of cancer patients has been greatly influenced by clinical trial outcomes. It demonstrates the effectiveness of current treatment and advantages of newer agents. This facilitates my discussions with the patient about available treatments, their benefits, and therapeutic adverse effects. Additionally, through conducting clinical trials, I have gained more experience on how to monitor and handle treatment adverse effects.

Through clinical research, we learn more about the efficacy, safety of medications and other treatment options. And I believe that without clinical trials, medical advancements would not be possible. Malaysia has intrinsic advantages for conducting clinical trials, such as its sizable multiethnic population that gives genetic variety. Furthermore, clinical trials also provide the opportunity for our patients to access newer treatments. And ultimately, the outcomes of a clinical trial will establish the standard of treatment, and I would like to play a role in that.

> **Malaysia has intrinsic advantages for conducting clinical trials as its sizable multiethnic population that gives genetic variety. Furthermore, clinical trials also provide the opportunity for our patients to access newer treatments**
>
> **Dr Chalaya Kumutha**

Dr Syafirin Bin Ab Sani
Clinical Oncologist

National Cancer Institute

My research interests are in the field of gastrointestinal, genitourinary and thoracic malignancy. I am also intrigued by the relationship between our immune system and its response to cancer cells.

I have no current research project ongoing, but my clinical goals are to improve upon wide variety of knowledge in oncology and gaining experience in managing cancer patients. Besides, recent clinical trials change the molecular and biomarker landscape and discovery of new treatment for the cancer patients

.

I have taken an interest and began my research in lung cancer immunotherapy treatment. In addition, I was involved in studying rare genetic malignancy. Clinical trial helps to increase our understanding in establishing new standard of care treatment and potentially guide future therapies.

> **My clinical goal are to improve upon wide variety of knowledge in oncology abd gaining experience in managing cancer patients. Besides, recent clinical trials change the molecular and biomarker landscape and discovery of new treatement for the cancer patients**
>
> **Dr Syafirin**

Dr Angel Kwan Khor Nee
Clinical Oncologist
Hospital Raja Permaisuri Bainun, Ipoh

I'm really intrigued by clinical research and pharmacology because they let me make a real difference in people's lives and improve healthcare. I'm especially interested in fixing healthcare inequalities linked to money and resources, by giving more people access to treatments. This field offers lots of different research chances and lets me have a big impact on medicine while helping the community.

Even though creating a new Oncology Unit at Hospital Raja Permaisuri Bainun is a lot of work, I'm still totally committed to clinical research. I want to be a good example and encourage my colleagues to move forward in their careers and get involved in research. Becoming a successful clinical oncologist and researcher needs a long-term commitment, being strong when things are tough, working hard, staying excited, and being good-hearted, truthful, and humble. I'm aiming to be great at these things and bring value to my profession and my country.

Clinical trials are super important for turning science into treatments and shaping the medicine industry. They give the best proof for treatments based on evidence and are key in making patients better and helping them survive. Making research important in healthcare places encourages curiosity, makes treatments better, and gives patients the best care.

I got more and more passionate about research during my medical studies and Clinical Oncology training at University Malaya. Learning about clinical trials in my training made me realize how important they are in making medicine better and taking care of patients. Seeing how positive it can be to be part of a clinical trial pushed me to want to help people's health, treatment results, and chances of getting better.

My family, including my uncle who's a spine surgeon, have always backed me up. He's been like a hero and guide to me, and their constant support makes me brave and sure of myself as I keep learning and getting better in my job.

I truly love being a clinical oncologist and I'm super excited to be a part of clinical trials as I move forward in my career. My aim is to do things that really help human health and keep pushing medicine forward.

Dr. Rangasamy Ramachandran
Clinical Oncologist
Hospital Sultan Ismail, Johor Bahru

I enrolled in several clinical trials during my postgraduate training which gave me great exposure to understand the importance of research and how to conduct clinical trials. This initiative has created a strong interest and passion in me until now in my daily clinical practice.

Clinical trials allow me to get exposure on trial drugs in terms of the response and potential adverse events. It also provides opportunity for patients to receive treatment which is proven to be safe especially those with rare cancer where options for standard systemic treatment are limited.

Cancer patients are my motivation. Oncology treatment is evolving in recent times so are the oncology drugs. It gives me job satisfaction to recruit my patients in clinical trials where I believe they will receive safe, better and new treatment. At the same time this allows me to understand and equip myself with the knowledge on the new study drug.

> **"It gives me job satisfaction to recruit my patients in the clinical trials where I believe they will receive safe, better and new treatment. At the same time this allows me to understand and equip myself with the knowledge of the new study drug"**
>
> **Dr Rangasamy**

CRM TRIAL CONNECT 2024

INFOGRAPHIC

RECRUITMENT ACHIEVEMENTS IN GLOBAL SPONSORED RESEARCH 2023

Global 1st Recruiter

Hospital Tengku Ampuan Afzan
Non-Small Cell Lung Cancer
Prof How Soon Hin

University Malaya Medical Centre
Non-Small Cell Lung Cancer
Dr. Tan Jiunn Liang

ASIA 1st Recruiter

Hospital Umum Sarawak
Non-Small Cell Lung Cancer
Dr Voon Pei Jye

Hospital Sultanah Aminah
Warm Autoimmune Hemolytic Anemia
Dr Azizan Bin Sharif

SEA 1st Recruiter

Institute of Respiratory Medicine
Idiopathic Pulmonary Fibrosis
Dr Syazatul Syakirin

Hospital Umum Sarawak
Atherosclerotic Cardiovascular Disease
Dr Diana Foo

APAC 1st Recruiter

Institute of Respiratory Medicine
Idiopathic Pulmonary Fibrosis
Dr Syazatul Syakirin

Hospital Tengku Ampuan Afzan
Non-Small Cell Lung Cancer
Prof How Soon Hin

Hospital Umum Sarawak
Advanced Solid Tumor (First in Human)
Dr Voon Pei Jye

Hospital Pulau Pinang
Hidradenitis Suppurativa
Dr. Tan Wooi Chiang

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

PARTICIPATING IN CLINICAL TRIAL - What you need to know

FEATURED SITE

Hospital Sultanah Nur Zahirah, Terengganu

Hospital Sultanah Nur Zahirah (HSNZ), situated in the Kuala Terengganu district on a sprawling 21.09-hectare site along Batu Buruk Beach, was formerly known as Hospital Kuala Terengganu. Its strategic location, facing the State Stadium (West), adjacent to Masjid Al-Muktafi Billah Shah (North), the Terengganu Hockey Stadium and Aquatic Complex (South), and overlooking the vast South China Sea (East), positions it as a prominent landmark in the region.

The renaming of the hospital was officially sanctioned by His Royal Highness Al-Wathiqu Billah Sultan Mizan Zainal Abidin Ibni Almarhum Sultan Mahmud Al-Muktafi Billah Shah, the Sultan of Terengganu, on December 2, 2006, corresponding to 11 Zulkaedah 1427H.

HSNZ Service and Development History:

- 1920: The hospital commenced its services with three wooden buildings.
- 1924: Services expanded with the construction of five new buildings.
- 1983: An 8-story new building was constructed as a 'Turnkey project' with a cost of RM 92.4 million.
- 2003: The Day Care Treatment Complex was completed with a cost of RM 39.3 million.

Departments, units and services available at HSNZ are listed below:

Clinical: Surgical Services

- Anaesthesiology & Intensive Care
- Ophthalmology
- Orthopaedic
- Plastic Surgery
- Otorhinolaryngology
- Emergency & Trauma
- Oral Surgery & Maxillofacial
- Paediatric Dentistry

Clinical: Medical Services

- Psychiatry & Mental Health
- Medical
- Dermatology
- Rehabilitation
- Nephrology
- Paediatric
- Obstetrics & Gynaecology

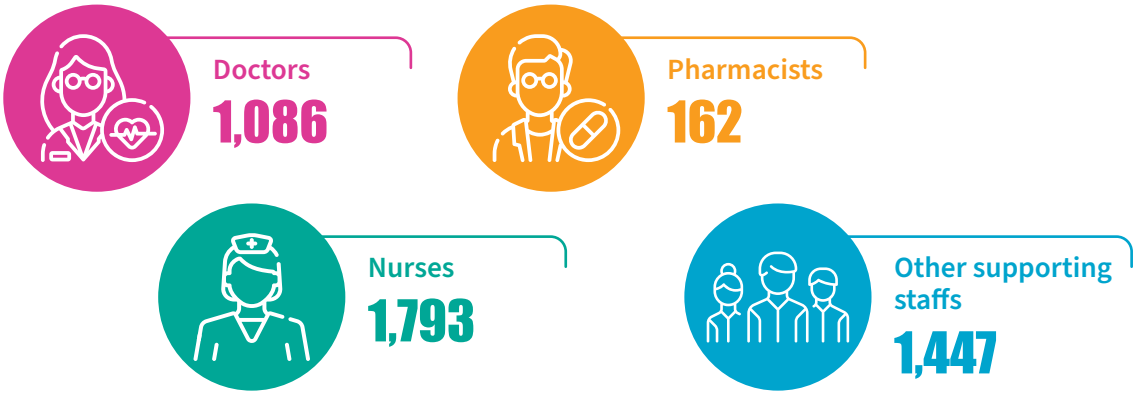
Support

- Quality
- Pharmacy
- Outpatient Department
- Dietetic & Food
- Medical Record Department
- Traditional & Complementary Medicine
- Nursing
- CSSD
- Unit Kesihatan Awam
- Unit Kesihatan Pekerja
- jabatan Kerja Sosial Perubatan
- Jabatan Pendidikan Kesihatan
- Jabatan Penyelidikan Kesihatan
- Unit Penyelia Hospital

Management

- Human Resource
- Finance
- IT
- Procurement
- Asset Development

Total Workforce/ Staff in Hospital Sultanah Nur Zahirah



Number of population served: 1.2 million

source: Terengganu (mycensus.gov.my)

Clinical Research Centre, HSNZ

CRC Hospital Sultanah Nur Zahirah was established in 2006 with the aim to encourage research at the hospital level and within the national level Network of Clinical Research Centres. Such activities are in line with the objectives of the Ministry of Health Malaysia with the purpose of generating research projects of quality.

The Hospital Sultanah Nur Zahirah Committee that oversees CRC HSNZ became effective in July 2006 while the office of CRC HSNZ began operating in December 2006. CRC HSNZ will provide support to all clinical research and clinical trial projects with the Network of CRCs in Malaysia.

Its main function is to establish a conducive environment to enable quality and ethical clinical research projects to be carried out to completion and to improve patient outcome in HSNZ, Kuala Terengganu. The Head of CRC HSNZ is Dr Khairul Azmi bin Ibrahim and he leads the team of 2 CRC Deputies, 1 Medical Officer, 1 Research Officer, 1 Research Nurse & 1 Research Assistant.

Sponsored Research Status (Jan 2022 - June 2023)						
Department	**Unit**	**On-going (maintenance & recruiting)**	**Start-up**	**Potential**	**Closed**	**Sub total**
Medical	Infectious Disease	1	0	0	4	5
	Hematology - Adult	1	1	0	1	3
	Neurology	2	0	0	2	4
	Cardiology	1	0	0	0	1
	Rheumatology	0	0	0	2	2
	Gastroenterology & Heptology	0	0	1	1	2
	Respiratory	1	1	1	0	3
Paediatric	Hematology - Paeds	1	0	0	0	1
	NA	0	0	0	1	1
Dermatology	NA	0	1	0	0	1
Nephrology	NA	1	0	0	0	1
Total		**8**	**3**	**2**	**11**	**24**

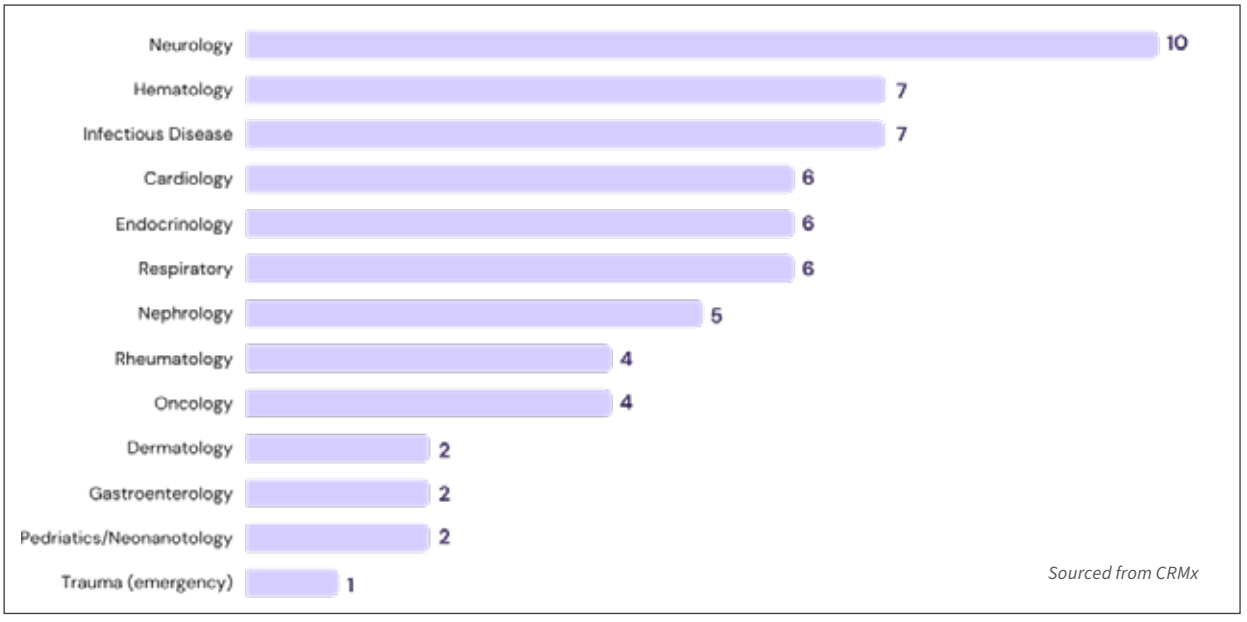


Figure 1: Sponsored Research at HSNZ by Therapeutic Area (2012 - 2023)

Clinical Research Achievements

Awarded certificate of excellence in recognition for the highest cumulative ISI impact factor for total publications per researcher among CRC Hospitals in 2018

2022 - C3601002: First Patient Randomized in Malaysia - Complicated Intra-abdominal Infection, Hosptial Acquired Pneumonia, Ventilator Associated Pneumonia

Dr Lau Hui Ting; 1st runner up for Young Investigator Award, 15th NCCR

PUBLICATIONS

Impact of Electronic Signature Towards Clinical Trial Agreements

Journal for Clinical Studies, Volume 14, Issue 6

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

The use of electronic signature is desirable for companies nowadays as technology has growingly become an integral part of our life. Not only that, implementing it can reduce the turnaround time and ensure business efficiency. Electronic signature is defined as a set of symbols or other data in digital form attached to an electronically transmitted document as verification of the sender's intent to sign the document.[1] It is a form of technology which allows you to sign a document via online. The legal definition of it is governed under Section 5 of the Electronic Commerce Act 2006, Malaysia (ECA 2006) where it states that 'Electronic Signature' is defined as any letter, character, number, sound or other symbol or combination thereof created in electronic form adopted by a person as a signature. And pursuant to Section 7 of the ECA 2006 a contract formed in accordance with the Contracts Act 1950, Malaysia through electronic communication is valid, binding, and enforceable by and on the contracting parties. In practice, most documents can be signed by form of electronic signatures however this is usually based on the discretion of the contractual parties.

Clinical Trial Agreements can be Signed Remotely

Traditionally, Clinical Trial Agreements (CTAs) were signed by way of wet ink as this is the most common method used to execute agreements. However, the COVID-19 pandemic has taken a toll towards how normal processes are usually managed. The impact of advanced technology in the world of signatures which is known as 'E-signatures' has paved a way for CTAs to be signed in a much convenient way as implementing electronic signatures can eliminate the need for the contractual parties to physically post the documents to sites which in effect will make the whole execution process more cost-saving. Not only that, but the signing parties can also sign the CTAs anywhere and they are able to use any type of electronic devices which the electronic signature software is compatible with. 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.

Expedite the Number of Days to Execute CTAs

Previously, it took more time for sites to sign a CTA, sometimes it could take several weeks for it to be executed. There are many possible factors which could affect the delay however the primary factor of it could be that the contractual parties are in different locations, so it takes a long time to complete the execution process as the CTAs must be posted to different places. However, with the implementation of electronic signature, the agreement can be signed promptly, and this could also avoid the risk of the agreements being lost during delivery as lost paper documents necessitate starting the signing process over again and this may increase the chance of legal liability.[2] In results, this could improve the start-up timeline of the CTAs which could be a driving factor for sponsors to do more clinical trials.

Minimise the Risk of Unauthorised Signing and Error in CTAs Execution Process

Utilising electronic signature in CTAs would help to minimise the risk of unauthorised execution of CTAs, especially when an electronic signature platform or software are used. This is because, most of electronic signature platform offers multiple options to verify the signatory's identity before they can sign the agreement, for example the signatory would have to enter a one-time passcode sent via text message or insert one time passcode provided by sender.

Besides that, this electronic signature platform provides certificate of completion of signatory, and they have an encryption software that able to verify the signatory's identity and provides an audit trail which is a digital log that archives when and where a document was viewed, signed and by whom it was signed[3] with real date and time stamp captured including the IP address of the signatory. This helps to verify the signature made in the CTAs where we could trace it back to the signatory and further this audit trail capability provides secure verification to fight against fraud as it is much harder to forge the signature since it can easily track the user IP address. Thus, this increased the evidential weight to the electronic signature process.

Further, through this electronic signature's platform, which can automatically detect even a minor altering,[4] we could easily identify and detect if there are any changes made by any of the parties prior to the signing as there is a record for any changes made to the agreement during or after signing.

Besides that, through the electronic signature platform, it helps us to identify any error made in signing of the agreement for example, it can detect when the signatory did not sign on the required intended part, inadvertently missed any required signature or even when it comes to the duplication of signature.[5] From this setting, we would be able to avoid any negligence or human error in the signing process and this will prevent the parties from having to send or post the CTAs again for re execution due to such error. This proved that using electronic signature will help to lessen and reduce the dispute arise concerning the authenticity and error in the execution process.

Better Recordkeeping of CTAs

By practising electronic signature, a better record management can be achieved. First of all, we are all aware that not every business has adequate storage space, and because working from home has become the norm, not everyone may have access to physical copies of the executed CTAs. Hospitals are also dealing with the same storage problem, particularly in government hospitals where patients take up a lot of space. Additionally, it is quite common in today's business world, particularly in large multinational pharmaceutical companies,for the contract manager or legal counsel to be located overseas; therefore, by using an electronic signature, the contract manager or the legal counsel would have quick access to the document in question. As such, with having electronic signature for the CTAs the same can be stored in common folder or shared drive where people who have the right to access can do so anytime and anywhere, they wish to. However, it should be highlighted that the record of the electronically signed CTAs should be made at the moment of the transaction or incident to which it pertains, or shortly thereafter, by people with first-hand knowledge of the facts, or using tools that are typically used by the company or organization to accomplish the transaction.

Secondly, because electronic storage is more durable, it can assure that the CTAs' signatures remain visible and traceable for many years to come. This is due to the fact that storing physical copies may cause the wet ink signature to fade over time, preventing parties fromexercising their rights when the time comes. Some clinical trials can last for several years, and some claims can be filed by a claimant even after the clinical experiment has physically ceased. Physical wet ink copies may potentially be lost in the event of a fire, flood, earthquake, or other uncontrollable force majeure event.

Thirdly, electronic storage of the electronically signed CTAs can aid in document verification. The electronically signed document will include a signature certificate that identifies the signatory, verifies the legitimacy of the digitised signature, and specifies the exact date and time the signatories signed the agreement.[9] With this, the integrity of the record is being complete and consistent provided always that the electronic storage via shared folder, OneDrive or any company's platform are made timely as mentioned above.

Conclusion

It is crystal clear that electronic signature practices will certainly benefit CTA parties. Accelerated timelines for completing CTAs execution will allow parties to start clinical trials as soon as possible, wherever they wish, without undue delay. Electronic signatures reduce the risk of losing physical documents or error in signing, and the confidentiality of contracts is protected by the practice of electronic signatures. In terms of recordkeeping, since the CTA is a very important legal document in clinical trials, an electronic record of the CTA with an electronic signature is a better choice.

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CRM Study Coordinators – Making Difference in Clinical Trial Conduct in Malaysia

Journal for Clinical Studies, Volume 15, Issue 1

Authors: Intan Munirah, Nor Hafiza, Venoo Kuppusamy, Joanne Yeoh

The clinical trial industry is developing rapidly in Malaysia. Since 2012 there have been more than 2000 clinical trials across different Therapeutic Areas, hence promoting Malaysia as a preferred country for sponsored clinical trials. The commitment to deliver clinical trials with Speed, Reliability and Quality is the essence to this success. This achievement is critically delivered by the invisible hands of Study Coordinators (SC).

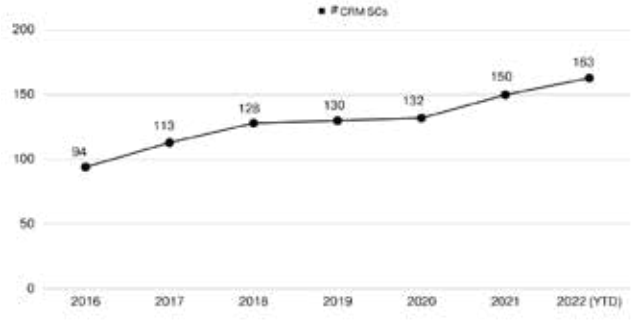
Although the Principal Investigators (PI) are responsible for the clinical trial conduct, very often the success of these studies relies on the study team which consists of SCs. SCs are specialised research professionals working with the PI to support, facilitate, and coordinate daily clinical trial activities and play a critical role in the conduct of the study. It is essential that SCs and PIs work hand in hand to ensure study conduct is in accordance with the protocol and principles of Good Clinical Practice (GCP).

CRM SCs support investigators at site to quicken the start-up process (from submission of Ethics Committee approval to site initiation) by assisting to collect and compile relevant documents within 14 days of request. The SCs are also trained to adhere to study timeline including PD reporting, SAE reporting, data entry etc. to ensure the study processes are carried out in a timely manner.

Growth of CRM Study Coordinators

A study published by Papke A. et. al shows that adding a coordinator to a research team significantly improves subject recruitment numbers, enhances subject retention, and increases general study efficiency[1].

In 2012, CRM had 22 SCs placed throughout Malaysia at various sites conducting industry-sponsored research; this number has grown to more than 160 SCs in 2022, placed mainly at Ministry of Health (MOH) hospitals, few MOH clinics and private hospitals. CRM has received increasing interest to support investigators and sites in Ministry of Higher Education (MOHE) hospitals and private hospitals over the years. The growth of CRM SCs over the span of 7 years is as illustrated in Graph 1.



Graph 1: Growth of CRM SCs over the last 7 years

CRM Initiative – Boosting Excellent Study Coordinator Service

In ensuring high quality SC service is provided to stakeholders, CRM conducts regular trainings and provides opportunities to further develop the SCs, continually evaluating the quality of service through Performance Management System (PMS) and treat customer's feedback as gold nuggets to be more effective in answering their needs.

a) Training for CRM SCs

The pharma industry does recognize that the performance quality of sites varies dramatically. Jim Kremidas, executive director of Association of Clinical Research Professionals (ACRP) believes the root cause of this variance is the lack of consistency in how staff, including principal investigators (PIs) and SCs at sites are screened, hired, trained, and validated for their competency[2].

With ISO 9001:2015, CRM has strengthened and standardized our services with proper Standard Operating Procedure (SOP) ensuring the right candidate is hired, trained and the delivery of the studies is similar across the country. Having an efficient SOP in place minimizes errors, clears the way forward by avoiding uncertainties, and serves as a vital tool to transfer knowledge and skill[3].

It is recommended GCP certified personnel to refresh their GCP every three years to stay updated with current regulations, standards, and guidelines[4]. CRM mandates that all SCs must be equipped with the adequate knowledge and GCP certification to perform their duties. Internal Post GCP Assessment Test (PGAT) is also incorporated as part of quality metrics to ensure SCs are tested on GCP knowledge every three years post GCP certification.

CRM has developed structural training programs to support the onboarding process for SCs especially those with no prior experience in clinical research. Training for SCs continues even after the probation period. This includes the yearly Training to Improve Performance of Study Coordinators (TIPS) introduced in 2019. The training modules are designed to meet expectation of the industry with support from Sponsors/CROs to deliver the trainings to SCs. There are also regional Continuous Medical Education (CME) conducted monthly for SCs to share their knowledge and best practices.

The continuous training also includes our in-house newsletter called "Q-Bites". It contains practical knowledge focussing on GCP, local Ethics Committee guidelines, regulatory guidelines in conducting high quality study which can be applied to SC's tumultuous daily life at work.

b) Adequate supervision by Line Manager

To ensure we maintain our service quality, the line managers conduct supervisory visits on quarterly basis to provide guidance and support to the SCs throughout the year. The work performance of the SCs is appraised by the respective line managers at least every 6 months through the structural mid-year performance and year-end performance review system.

c) Opportunities for career development

CRM creates opportunities for the SCs to grow their careers in a transparent, competence-based systems as depicted in Diagram 2. These career tracks allow CRM to increase job satisfaction of the SCs as each employee can grow their individual passion and career.

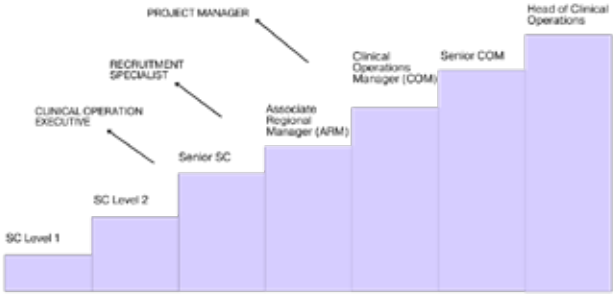


Diagram 2: Career Advancement Ladder for SCs within Clinical Operations Department

Customer Satisfaction Survey on SC Services

In 2021, CRM conducted Customer Satisfaction Survey (CSS) through a third-party company, Vase.ai. The online survey was conducted between Dec 2021 and Jan 2022. The nationwide survey covered four services provided by CRM including the Study Coordinator service. 234 respondents from stakeholders such as Investigators, Sponsors and CRO have taken part in the survey and the detailed breakdown is as shown in Figure 1.

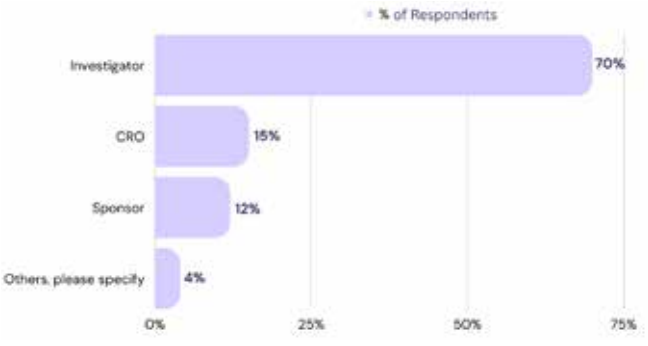


Figure 1: Respondents for Customer Satisfaction Survey 2021

211 out of 234 respondents have experience in engaging with CRM SCs for their clinical trials. The respondents rated CRM SCs performance at site on three areas:

1. Knowledge and compliance of study protocol and GCP.
2. SC's competency in performing delegated tasks and helpfulness in subject recruitment activities.
3. Speed/responsiveness to perform delegated tasks and maintenance of Investigator Site File (ISF) within the timelines.

Besides that, this electronic signature platform provides certificate of completion of signatory, and they have an encryption software that able to verify the signatory's identity and provides an audit trail which is a digital log that archives when and where a document was viewed, signed and by whom it was signed[3] with real date and time stamp captured including the IP address of the signatory. This helps to verify the signature made in the CTAs where we could trace it back to the signatory and further this audit trail capability provides secure verification to fight against fraud as it is much harder to forge the signature since it can easily track the user IP address. Thus, this increased the evidential weight to the electronic signature process.

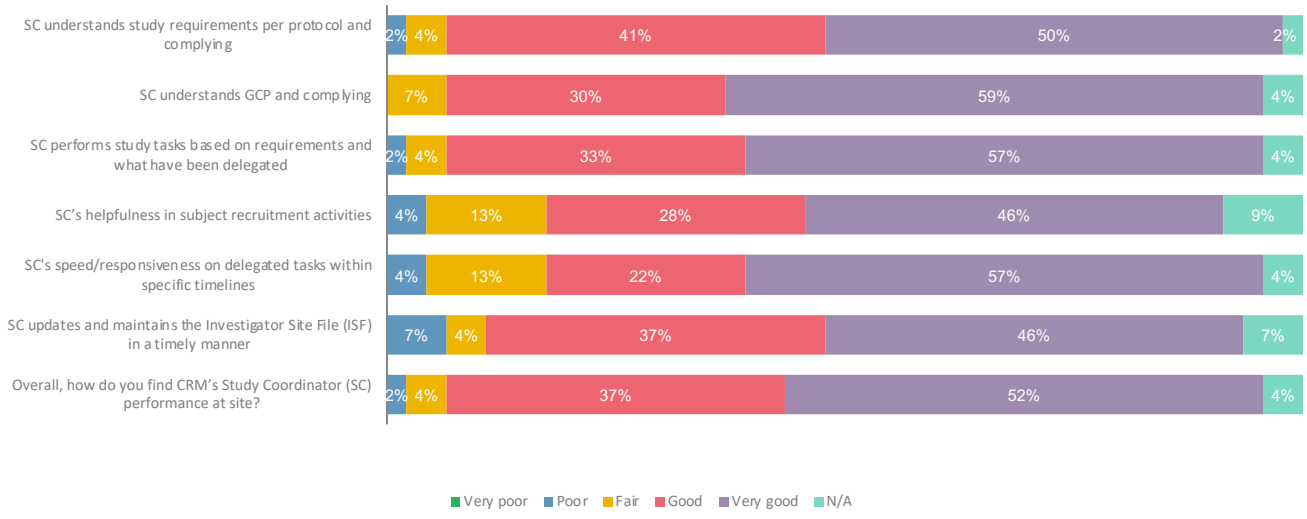


Figure 2: Respondents Rating

Through the initiatives conducted by CRM, the customers gave 89% satisfactory rate (rated 'Good and above') towards CRM SC services. Feedback was received that the top three areas for improvement are related to workload management, retention of SCs and training and development. CRM values the feedback from respondents and has taken action to mitigate the issues. One of the new strategies introduced in 2022 is the hiring of additional SCs that are mobile and support site with high activities. New trainings including effective communication was carried out to improve the communication skills of the SCs. In addition to this, CRM credits the outstanding performance of the company to its people. The people are the greatest asset to the organisation and CRM has implemented new schemes in 2022 to improve the employee's status and benefit in the company.

Conclusion

The SCs are the invisible hands in clinical trials who contributes to the success of each trial and provides supports to the Investigators. Finding qualified candidates for SC position can be quite challenging[5]. However, with proper skills and knowledge equipped to each SC by CRM, they can carry out the clinical trials not only at a high quality, but also maintain high integrity throughout the trial conduct.

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CRM IN PHOTOS

Meeting with ClinActis

16 Jan

Meeting with Roche Diagnostics

17 Jan

Meeting with AGTC

7 Feb

Educational Session at University of Nottingham

8 Feb

Meeting with Docquity

8 Feb

Meeting with Mr Aaron Kual, Health Adviser, British High Commission KL

9 Feb

IAA roadshow at Hospital Ampang

14-15 Feb

Meeting with Karger Publisher

22 Feb

Meeting with IED Healthcare

23 Feb

Meeting with BeiGene

3 Mar

Meeting with Pantai Medical Centre

3 Mar

IAA roadshow at Hospital Selayang

15-16 Mar

CRM IN PHOTOS

Meeting with Cell Biopeutics Resources

17 Mar

Meeting with St George's University of London

20 Mar

Meeting with BioKorea Co. & IMR

23 Mar

Meeting with Integral Omni Inspire

24 Mar

Meeting with CanSinoBIO

5 Apr

Meeting with IQVIA

10 Apr

Meeting with DNDi

17 Apr

Meeting with Neuome Peptides

17 Apr

Meeting with PhAMA

17 Apr

Meeting with Takeda

17 Apr

Meeting with KPJ Healthcare Uni College

18 Apr

Meeting with Zuellig Pharma

18 Apr

CRM IN PHOTOS

Meeting with Technology Depository Agency (TDA)

15 May

Meeting with MSD led by Andy Lee, Senior Vice President, Head of Global Clinical Trial Operations.

16 May

IAA Roadshow at Pantai Hospital Kuala Lumpur

18-19 May

Meeting with AstraZeneca

23 May

IAA Roadshow at Klinik Kesihatan Kuang, Rawang

7-8 June

Meeting with Dato' Dr Jacob Thomas, Group Medical Advisor of Ramsay Sime Darby Health Care

16 June

Sungai Buloh State Research Day

16 June

Meeting with Mr Victor Cirne, the Second Secretary of the Embassy of Brazil.

19 June

Meting with Management & Science University (MSU), led by Prof Datuk Dr Hj Rohaizat (MSU Board of Governor)

19 June

Meeting with Pure Collective Singapore

19 June

Meeting with Baden Research & Testing Lab, led by Prof Dato' Sri Dr Mike Chan

21 June

Meeting with MediqTrans

22 June

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