

BY CLINICAL RESEARCH MALAYSIA

CRM Bulletin

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FROM LOCAL IMPACT TO GLOBAL MOMENTUM

RESEARCH PERSONALITY
DR AZURA MOHD AFFANDI

FEATURED SITE

- **Sarawak General Hospital**
- **Ampang Hospital**

RISING STARS
IN **DERMATOLOGY**





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.



From The CEO's Desk



Welcome to the final Bulletin issue of 2025.

As we close this remarkable year, I am filled with gratitude for what we have collectively achieved. The final quarter has been extraordinary; marked by unprecedented momentum, meaningful partnerships, and tangible impact beyond our borders.

CRM remained relentless in positioning Malaysia as a preferred clinical research hub. We completed our eighth I AM AWARE Roadshow, empowering communities with knowledge about clinical trials, while SCAP Batch 3 successfully graduated, strengthening our workforce for the future. Critical international partnerships were forged; hosting Japan's PMDA, engaging with Peter MacCallum Cancer Centre, and formalising our GARDP collaboration on antimicrobial resistance research. Our presence at ESMO Congress in Berlin, ESMO Asia in Singapore, and ICN Shanghai reinforced Malaysia's growing credibility in oncology and early-phase research.

The launch of our Penang Operations Office and UMMC's Phase I Unit mark pivotal moments in strengthening Malaysia's early-phase capabilities. Achieving zero non-conformities in both ISO audits reflects our unwavering commitment to operational excellence. As IQVIA's latest white paper recognises Malaysia as an emerging preferred hub for early-phase clinical trials, we stand at an inflection point. The ecosystem we have nurtured; built on Speed, Reliability, and Quality, guided by Humanity, Stability, and Sustainability, is gaining global recognition and delivering real impact for patients.

As we step into 2026, we carry forward the momentum gained. Together, we will continue advancing Malaysia's clinical research landscape, bringing hope and innovative treatments to patients who need them most.

Thank you for being part of this journey.

Dr. Akhmal Yusof
CEO, Clinical Research Malaysia

www.clinicalresearch.my

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HIGHLIGHTS



I AM AWARE Roadshows

3-4, 22-23 September & 7 November 2025 – CRM successfully concluded its all 8th I AM AWARE Roadshows of the year at Melaka Hospital, Sultanah Aminah Hospital and Tuanku Ja'afar Hospital. The programmes served as impactful platforms to engage with the public, raise awareness, and highlight the importance of clinical research. These initiatives reflect CRM's ongoing commitment to fostering greater understanding and participation in clinical research across Malaysia.



KoNECT International Conference 2025

22-24 September 2025 - CRM joined the KoNECT International Conference 2025 in South Korea, the world's 6th largest sponsored clinical research market with over 700 trials conducted annually. The conference provided valuable insights into Korea's strong infrastructure and support systems, offering lessons that Malaysia and the wider Southeast Asia region can leverage to advance clinical research capabilities.



ASCOMOS 2025: Advancing Oncology Together

30 September 2025 – CRM was honoured to join the 36th Annual Scientific Congress of the Malaysian Oncological Society (ASCOMOS 2025) in Johor Bahru, held under the theme "Goals of Hope: Advancing Oncology Together." The congress offered a valuable platform to connect with stakeholders, exchange knowledge, and explore the latest developments in oncology management and treatment innovations. We look forward to the next edition at ASCOMOS 2026, which will be held in conjunction with the 59th Malaysia-Singapore Congress of Medicine.



CRM Hosts Japan's PMDA to Advance Regional Clinical Research

30 September 2025 - It was a great honour for CRM to host Dr Yasuhiro Fujiwara, Chief Executive Officer of Japan's Pharmaceuticals & Medical Devices Agency (PMDA), and his team at CRM Headquarters. PMDA has long been a driving force in advancing regional regulatory harmonisation through trainings and collaborations. With Asia First as one of its key pillars, PMDA recognises ASEAN's immense potential and is eager to strengthen collaborations with stakeholders across the clinical research ecosystem to further expand ASEAN and Asia's presence in global clinical trials.



Strengthening Regional Ties in Clinical Research

3 October 2025 - CRM CEO Dr Akhmal Yusof and Clinical Operations Manager Ms Shakirin Kamaruzaman visited the Siriraj Institute of Clinical Research (SICRES) in Bangkok, where they met Professor Dr Apichat Asavamongkolkul, Dean of the Faculty of Medicine. The visit fostered discussions on advancing clinical research collaboration in Southeast Asia. CRM thanks SICRES for their warm hospitality and looks forward to continued partnership.



Healthy Volunteers Forum & I AM AWARE

15 October 2025 - CRM was honoured to be part of the Healthy Volunteer Forum 2025 at Hospital Ampang, officiated by Datuk Dr Nor Fariza Ngah, which brought together healthcare professionals, researchers and volunteers to recognise the vital role of healthy volunteers in clinical research. Ms Khadijah Sakaria from CRM shared insights on “Opportunities Ahead – How to Join & Stay Engaged in Research,” marking our sixth I AM AWARE Roadshow of the year. Congratulations to Hospital Ampang for organising a meaningful event that celebrated and inspired participation in research for better health.



Strengthening Regional Collaboration through ARISE

16 & 17 October 2025 - Throwback to the 4th ARISE Annual Meeting, hosted by Nagasaki University, Japan. Exciting times ahead with ARISE approaching its ESBL study initiation across multiple sites within its ARO network. Malaysia was represented by both its members institutions (CRM & UMMC), with CRM sharing its ongoing initiatives in expanding community awareness on clinical research as well as its capability enhancement programs within CRM's Centre of Excellence. Much to look forward to in collaborations within member institutions, especially in growing capabilities together and strengthening ARISE as a front-runner in international research.



Datuk Dr Radzi Honoured with RCSI Lifetime Achievement Award

18 October 2025 - CRM congratulates Datuk Dr Muhammad Radzi bin Abu Hassan on receiving the RCSI Alumni Lifetime Achievement Award 2025. A distinguished clinician and former Director-General of Health Malaysia, his leadership in healthcare policy, clinical research, and treatment access especially in hepatitis C and gastroenterology has strengthened Malaysia's global health presence.



CRM at ESMO 2025: Advancing Malaysia's Role in Global Oncology

17-21 October 2025 – The CRM team attended ESMO Congress 2025 in Berlin, connecting with over 35,000 oncology professionals and global pharma leaders. Discussions highlighted Malaysia's clinical research capabilities, experienced investigators, and high-performing trial sites, fostering opportunities for multinational oncology trials. Malaysian oncologists were also recognised as co-authors in several presented trials, showcasing Malaysia's growing role in global cancer research.



Empowering the Lupus Community Through Clinical Trial Insights

25 October 2025 – CRM proudly participated in the SLE Symposium 2025, organised by Persatuan SLE Malaysia, where Dr. Shereen Ch'ng Suyin shared a presentation titled "Clinical Trials in SLE: A Guide for Patients" with over 100 attendees, fostering greater understanding of Systemic Lupus Erythematosus and advancing knowledge on patient care and research developments.



Advancing Collaboration at the ICN Annual Meeting

27 October 2025 – CRM participated in the ICN Annual Meeting in Shanghai, where global clinical research centres shared insights on advancing ISR. Highlights included Thailand's initiatives inspired by Malaysia's one-stop model, updates on ethics review and ICH GCP alignment, and CRM's progress in legal CTA review to streamline study start-up timelines. Representatives from Malaysian and international CRCs joined the discussions.



Advancing Hope for Thalassemia Patients

1 November 2025 – The 2nd National Conference for Thalassaemics and Carers, officiated by the Minister of Health, brought together patients, caregivers, and healthcare professionals to strengthen collaboration in thalassaemia care. With haematology trials making up 4% of Malaysia's clinical research landscape, CRM remains committed to working alongside dedicated investigators and partners to expand access to innovative treatments for thalassaemia patients.



Strengthening Global Collaboration in Cancer Research

11 November 2025 – AACR on Campus Malaysia 2025, organised by Cancer Research Malaysia, convened leading minds in cancer research for a day of learning and collaboration. The program featured Prof Timothy Yap from MD Anderson Cancer Center, who shared insights on personalised cancer therapy and translational research, propelling capability development for Malaysia and Southeast Asia in advancing cancer innovation.



CRM Achieves Zero Non-Conformities in ISO 9001 and ISO 37001 Audits

12 November 2025 - CRM successfully completed the ISO 9001:2015 (Quality Management System) and ISO 37001:2016 (Anti-Bribery Management System) surveillance audits with zero non-conformities, reflecting the dedication of our team to uphold the highest international standards and reinforcing our commitment to speed, reliability, quality, trust, and transparency across all operations.



Cultivating Sustainability: CRM Expands Green Initiatives at Taman Tugu

12 November 2025 - CRM continues its sustainability journey by planting ten additional trees at Taman Tugu, Kuala Lumpur, reinforcing our commitment to the environment and community, while the CRM Sports and Recreational Club celebrated the occasion with a TreeSure Hunt, promoting teamwork, fun, and a greener future.



Exploring R&D Collaborations: CRM's Delegation to South Korea

13 November 2025 - CRM was part of an 8-member delegation to South Korea organised by MIDA to explore R&D collaborations and investment opportunities with pharmaceutical partners, engaging with industry leaders like Hanmi Pharmaceuticals, Chong Kun Dang, Korean United Pharma, and LSK Global, while highlighting Malaysia's strong global clinical trial footprint and supportive ecosystem focused on speed, quality, and reliability in healthcare and clinical research.



CRM Engages with Indonesia’s Health Minister to Strengthen Regional Clinical Trials

17 November 2025 - CRM had the honour of meeting Indonesia’s Minister of Health, Yth Mr Budi Gunadi Sadikin, to share insights from Malaysia’s clinical trial journey and discuss Indonesia’s progress under INA-CRC, highlighting Southeast Asia’s potential to accelerate innovation and patient impact. Post the meet, CRM visited the Eijkman Building at RSCM, which is the base for the nation’s Biomedical & Genome Science Initiative.



Strengthening Collaboration to Expand Patient Access to Innovative Treatments

26 November 2025 - CRM welcomed the BeOne Leadership team, led by Dr. Wu Xiaobin (President & COO), for a visit to Sarawak General Hospital and its Phase 1 accredited unit. The meet fostered meaningful exchanges and laid the groundwork for future collaborations aimed at enhancing patient access to treatments in line with our principles of humanity, stability, and sustainability.



CRM Showcases Malaysia’s Clinical Research Strengths at MIH Megatrends 2025

25-27 November 2025 - CRM was honoured to participate in the Malaysia International Healthcare (MIH) Megatrends 2025 at the Kuala Lumpur Convention Centre, joining healthcare leaders, policymakers, and innovators to explore emerging trends shaping a healthier, more sustainable future, while showcasing Malaysia’s strengths as a preferred clinical trial hub and reaffirming CRM’s commitment to advancing healthcare access, innovation, and clinical research outcomes for Malaysians.



Strengthening Global Clinical Research Partnerships with Monash University and Monash Health

2 December 2025 - CRM’s visit to Melbourne marked a meaningful step in advancing global research collaborations, with productive engagements at Monash University’s Faculty of Pharmacy and Pharmaceutical Sciences, School of Public Health and Preventive Medicine, and Monash Health, where valuable exchanges highlighted strong alignment in clinical trials, drug discovery, public health research, and innovation—opening new pathways for collaboration, capacity building, and research excellence to benefit patients in Malaysia and the region.



CRM Strengthens Collaboration with Peter MacCallum Cancer Centre

2 December 2025 – CRM's ongoing engagement with Peter MacCallum Cancer Centre reached a new milestone with a recent visit to its Melbourne facility, paving the way for an upcoming traineeship programme for Study Coordinators and reinforcing shared commitments under CRM's Vision 2033 to strengthen the clinical research profession and build highly capable early-phase trial teams.



CRM and GARDP Formalise Partnership to Strengthen AMR Research

5 December 2025 – CRM has formalised a Memorandum of Understanding with the Global Antibiotic Research & Development Partnership (GARDP), marking a key milestone in strengthening Malaysia's role in addressing antimicrobial resistance through the SECURE project by advancing research capabilities, building local expertise, and supporting sustainable and equitable access to essential antibiotics.



Building Bridges for the Arthritis Community

5 December 2025 – CRM had a productive meeting with Dr. Fariz Yahya, President of the Arthritis Foundation Malaysia, to discuss potential collaboration opportunities and future initiatives for the arthritis community. The discussion centered on shared objectives including raising awareness about arthritis, empowering patients with knowledge and resources, and strengthening support networks. These collaborative efforts aim to improve the quality of life for individuals living with arthritis across Malaysia.



Malaysia Showcases Rising Oncology and Early-Phase Research Strength at ESMO Asia 2025

7 December 2025 - Clinical Research Malaysia's participation at ESMO Asia 2025 in Singapore highlighted the nation's growing momentum in oncology and early-phase clinical research, with meaningful engagements alongside global partners, new trial discussions, and strong representation by Malaysian investigators on the regional stage—reinforcing Malaysia's emergence as a credible and rising contributor to the future of cancer innovation in Asia.

SPOTLIGHT FEATURE

New CRM Penang Office to Accelerate Growth of Sponsored Clinical Trials in Malaysia



Georgetown, Penang, 25 Nov 2025 – Clinical Research Malaysia (CRM) officially launched its new Penang Operations Office, officiated by the Minister of Health and CRM Chairman, YB Datuk Seri Dr Dzulkefly Ahmad. The expansion marks a significant step in strengthening Malaysia’s clinical research capacity and supporting the growing number of clinical trials in the northern region. Over the past three years, 723 industry-funded clinical trials were recorded nationwide, generating RM665 million in Gross National Income and creating more than 3,000 skilled jobs in clinical research.

The new office will serve as the base for 24 CRM personnel dedicated to supporting clinical trials at Penang General Hospital—Penang’s most active trial site, where 80% of the state’s sponsored trials are conducted. A significant number of these studies focus on pioneering cancer therapies, offering patients with unmet needs early access to some of the most innovative treatments on the horizon. Penang remains a major contributor to Malaysia’s clinical research landscape, accounting for one in four sponsored clinical trials conducted nationwide.



Earlier in the day, Dr Dzulkefly chaired the CRM Board of Directors meeting, which highlighted Malaysia’s strong trajectory in clinical research, alongside ongoing strategic efforts to attract more global studies to the region.

“I am encouraged by CRM’s growing regional influence, especially through initiatives like the CRM Trial Connect Conference and the organisation’s leadership in positioning clinical research as a catalyst for ASEAN’s economic and scientific advancement,” said Dr Dzulkefly. “These efforts elevate Malaysia’s standing and reinforce our capability to shape the future of clinical trials in Southeast Asia.”

The event also recognised excellence among CRM’s workforce, with six CRM study coordinators receiving the Johnson & Johnson Certificate of Appreciation for their outstanding performance in high-quality trial delivery.

With Penang emerging as a key hub for diverse therapeutic research, the new CRM Penang Office will further strengthen site support, deepen clinical investigator engagement, and widen career pathways within Malaysia’s growing clinical research ecosystem.

RESEARCH PERSONALITY



Dr Azura Mohd Affandi

Head of Dermatology Subspecialty, Ministry of Health Malaysia.

Consultant Dermatologist and Head of Dermatology Department, Hospital Kuala Lumpur.

About Dr Azura

Dr. Azura Mohd Affandi is a Consultant Dermatologist and Head of the Dermatology Department at Hospital Kuala Lumpur. She also serves as the Head of the Dermatology Subspecialty under the Ministry of Health, Malaysia, and maintains a parallel practice in private healthcare institutions across the country. Dr. Azura obtained her medical degree from the University of Manchester, United Kingdom. She is a member of the Royal College of Physicians (MRCP, UK) and completed her Advanced Master of Dermatology at the National University of Malaysia.

With over 15 years of experience in managing a wide range of dermatological conditions, Dr. Azura also contributes to the training and mentorship of Advanced Master of Dermatology candidates in Malaysia. In addition, she has served as the Medical Advisor to the Psoriasis Association of Malaysia for the past decade, supporting patient advocacy and outreach. An active participant in clinical research, Dr. Azura has led several multi-centre clinical trials as a site principal investigator, further advancing the field of dermatology through evidence-based practice.

Can you tell us your journey as a principal investigator?

I started a little later than most. For many years, my focus was entirely on clinical work, and research had to take a back seat. In 2020, an opportunity arises to lead a clinical trial for a rare and severe skin condition — generalised pustular psoriasis. It happened to coincide with the start of the COVID-19 pandemic, at a time when the whole world was going into quarantine. It was a challenging period, but also a turning point. That first study opened the door for me to step into the world of clinical research and discover how impactful and fulfilling it can be.

What are the biggest challenge you have encountered when conducting a clinical trial and how did you overcome them?

Patient recruitment and retention are always the biggest hurdles. Many patients hesitate to participate, often worrying that they will be treated like “lab rats.” Those who eventually

join may struggle with the demanding follow-up schedules, sometimes as frequent as every two weeks.

Another challenge arises when a trial is discontinued by the sponsor due to lack of efficacy. Communicating this to patients, especially those who have invested time, hope, and commitment can be difficult and requires sensitivity and clear explanation. On my end, juggling trial visits alongside routine clinical duties, teaching dermatology master students, and managing administrative responsibilities can be overwhelming.

What helps me overcome these challenges is building strong rapport with patients, ensuring they feel supported throughout their journey, and working with a committed research team who understands the importance of timely follow-ups.

What motivates you to conduct clinical trials?

For me, it's a combination of purpose and passion. Clinical trials give my patients access to innovative and often very costly treatments that they might not otherwise be able to receive. They also allow me to contribute Malaysian data to the global evidence base, which is something I feel strongly about.

I am motivated by the opportunity to collaborate with experts both locally and internationally, to engage in meaningful scientific discussions, and to present or publish our findings.

Ultimately, clinical research allows me to create impact beyond the clinic room and to play a small role in advancing dermatology care for future patients.

Can you tell us your current areas of interest in research?

My main research interests include psoriasis and hidradenitis suppurativa. I am also keen to expand into urticaria, atopic eczema, vitiligo, and skin cancers if the right opportunities arise. These are areas where Malaysian data is still limited, and I hope to contribute to closing those gaps.

Tell us an unforgettable experience or accomplishment as an investigator?

The most rewarding experience is seeing a patient's skin improve and witnessing how dramatically their quality-of-life transforms. Nothing compares to that sense of fulfilment. Professionally, being invited to present at international conferences has been a tremendous honour, and being appointed as a Councillor for the International Psoriasis Council remains one of my proudest milestones. I am also grateful for the opportunity to publish in a high-impact journal alongside reputable and highly respected authors — an achievement that has been both humbling and motivating. These experiences affirm the value of the work we do and continue to drive me to push the boundaries of dermatology research.

What is your personal vision as an investigator?

My vision is to strengthen Malaysia's presence in high-quality dermatology research, especially for diseases that are rare, severe, or under-represented. I hope to build a research ecosystem where clinicians, trainees, and industry partners can work together seamlessly, and where more patients benefit from cutting-edge therapies. I also want to mentor younger dermatologists so that the next generation can lead even more impactful studies.

In the field of dermatology, what do you feel are the biggest challenges today, and what changes or advancements would you like to see in the coming years?

One of the biggest challenges is ensuring equitable access to advanced treatments, especially biologics, for patients across different regions. Another challenge is the rising burden of chronic inflammatory skin diseases, which require long-term, holistic management.

In the coming years, I hope to see:

- More affordable pathways for patients to receive effective treatments
- Stronger collaboration between dermatology centres to conduct multicentre studies
- More local data on Asian skin types and disease patterns
- Greater public awareness to reduce stigma around visible skin diseases

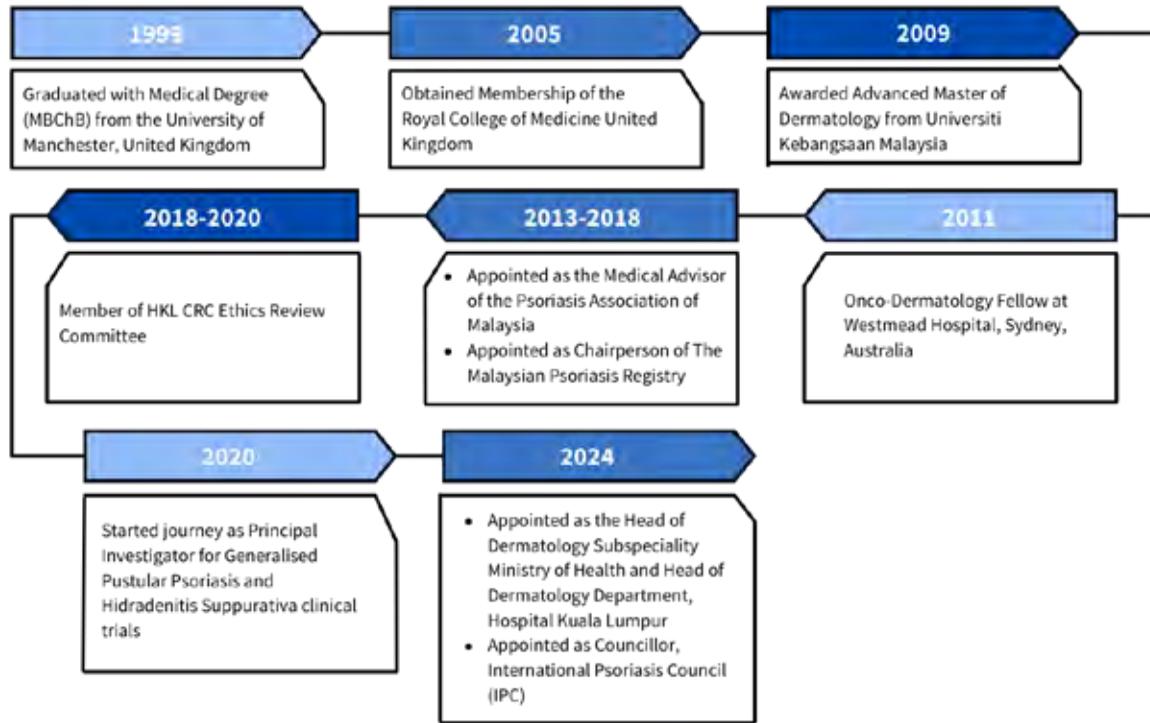
These advancements would elevate dermatology care for Malaysians.

Can you give word of advice for those who want to begin their career in clinical research?

Start small, but start early. Look for mentors who are active in research, volunteer to assist in trials, and learn the workflow from the ground up. Clinical research is teamwork — you don't have to know everything at the beginning.

Be curious, be patient, and don't be afraid of challenges. The learning curve is steep, but the impact on patients and your own professional growth makes the journey truly worthwhile.

DR AZURA'S ROADMAP AS AN INVESTIGATOR



CLINICAL RESEARCH EXPERIENCE

Principal Investigator

Handled 7 Industry Sponsored Research studies

CURRENT AREAS OF INTEREST IN RESEARCH

- Plaque psoriasis
- Generalized Pustular Psoriasis
- Hidradenitis Suppurative
- Atopic Dermatitis
- Acne vulgaris
- Cutaneous Lymphoma and other skin cancer



Dr Azura and her study team

RISING STARS IN DERMATOLOGY

From 2012 to 2025, a total of 234 dermatology studies were conducted in Malaysia, reflecting consistent growth in dermatology clinical research and strong collaboration across the clinical research ecosystem. The research focuses on major inflammatory skin diseases such as atopic dermatitis, psoriasis (including generalized pustular psoriasis), hidradenitis suppurativa, and chronic urticaria, as well as selected rare conditions including systemic sclerosis, vitiligo, and Netherton syndrome, alongside studies on wound healing, pigmentation, skin barrier function, and skin regeneration.

Dr Chia Jian Qin

Dermatologist & Head of Dermatologist Department

Sultanah Fatimah Specialist Hospital Muar, Johor Bahru



Dr Norazura Mohamad

Consultant Dermatologist & Head of Terengganu Dermatology Services/ Head of Dermatology Department

Sultanah Nur Zaharah Hospital



Areas of Interest in Research

Clinical dermatology, inflammatory skin diseases, and contact dermatitis.

I am involved in several key research initiatives, including a national contact dermatitis registry that gathers patch-test data from hospitals across Malaysia to identify regional allergen trends and improve standardisation, prevention, and workplace safety. I also serve as principal investigator for sponsored clinical studies on remibrutinib and the IRASPEN Psoriasis Registry, and previously as a sub-investigator in a long-term study on spesolimab for generalised pustular psoriasis.

Becoming a principal investigator at a district hospital has been a major career highlight, showing that high-quality research is not limited to large urban centres and allowing patients in towns like Muar to access new treatments locally. Currently, many local dermatology studies are small and single-centre, highlighting the need for larger, multi-centre collaboration across Malaysia.

More data are needed on contact dermatitis and occupational skin disease due to regional allergen differences, as well as real-world psoriasis outcomes, paediatric atopic dermatitis, cutaneous drug reactions linked to newer therapies, and pigmentary conditions in Asian skin. Accessible registry systems are essential so hospitals of all sizes, including district hospitals, can contribute to national data. With greater collaboration and shared data, we can strengthen Malaysia's research culture and better reflect real-world clinical challenges.

Areas of Interest in Research

Autoimmune diseases

My medical journey began with an MD from the National University of Malaysia (UKM) in 2003, followed by postgraduate training and a Master of Internal Medicine from Universiti Sains Malaysia (USM) in 2012. Pursuing my interest in skin diseases, I later obtained an Advanced Master of Dermatology from UKM in 2016.

My commitment to patient care and institutional service has been recognised with Excellence in Service Awards in 2007 and 2017, reflecting my dedication to high professional standards.

Alongside clinical practice, I have been actively involved in clinical research since 2017, with a strong interest in the pathogenesis and treatment of autoimmune and inflammatory skin disorders. Since 2022, I have also participated in industry-sponsored research, contributing to the development of innovative therapies through collaborative work.

I remain committed to using my clinical experience and research involvement to advance dermatology, patient care, and medical knowledge.

Dr Tzyy Huei Lim

Consultant Dermatologist
Sarawak General Hospital



Areas of Interest in Research

Pustular psoriasis, chronic spontaneous urticaria & hidradenitis suppurativa

Since beginning my research journey in 2020, I have conducted six sponsored research projects, published 12 academic journal articles, delivered three oral presentations, and presented six posters. One of my most meaningful achievements as an investigator has been identifying new therapeutic approaches for patients with refractory skin conditions and seeing their symptoms finally come under control.

Hidradenitis suppurativa (HS) is an area that urgently needs more research due to the lack of a cure, delays in diagnosis, and limited effective treatments. Management often requires multidisciplinary care, off-label therapies, or surgery, yet many patients continue to experience pain, scarring, and psychological impact.

My interest in becoming a principal investigator began while serving at the visiting skin clinic at Hospital Sultanah Nora Ismail from 2016 to 2019 under the mentorship of Dr. Evelyn Yap, where I conducted retrospective studies and completed my first publication. In 2020, under the guidance of Dr. Pualan, I became involved in industry-sponsored research and progressed from sub-investigator to principal investigator in 2023. I am grateful to my Head of Department, Dr. Tang, and Hospital Director, Dr. Ngian, for supporting my research alongside clinical duties.

Balancing clinical and research work can be challenging, and I am deeply thankful to my patients for their trust and willingness to participate in my studies—some even travelling long distances to Sarawak General Hospital. Their support has made my research journey possible.

Dr Tan See Ling

Consultant Dermatologist
Selayang Hospital



Areas of Interest in Research

Psoriasis, atopic dermatitis, Autoimmune blistering diseases & connective tissue disease-related dermatoses

I am a board-certified dermatologist with over 15 years of clinical experience and specialized training in dermato-immunology from the National Skin Centre, Singapore. I hold an Advanced Master of Dermatology from Universiti Kebangsaan Malaysia, MRCP (London), and a Certificate in Chronic Inflammation and Autoimmune Therapy from Harvard Medical School.

Currently serving as Consultant Dermatologist at Hospital Selayang and Visiting Consultant at KPJ Rawang Specialist Hospital, I have led 4 major clinical trials in inflammatory skin conditions including psoriasis, atopic dermatitis, and hidradenitis suppurativa. My research contributions include 2 peer-reviewed publications and over 10 presentations at international conferences.

Recent Achievements:

- My case report on dupilumab therapy was accepted for the 2026 AAD Annual Meeting Scholarship
- Selected as Selangor State Champion for the 2026 Psoriasis Clinical Practice Guideline Training
- Active reviewer for the Journal of Asia Pacific Aesthetic Sciences

I am inspired by my passion to translate science into better patient outcomes. Seeing how skin diseases affect lives motivates me to contribute to research that advances safer, more effective treatments. Clinical research allows me to represent Malaysian patients in global studies and ensure our diversity is reflected in evidence-based care. I aspire to drive innovation, uphold research integrity, and mentor future investigators in dermatologic science.



7-8 May 2026 | Connexion Conference & Event Centre, Kuala Lumpur

Program Collaborators



Collaborating Event



REGISTRATION IS NOW OPEN!
To register/for more information, visit
www.crmtrialconnect.com

FEATURED SITE

First-in-Human sites in Malaysia



Sarawak General Hospital

The Clinical Research Centre Sarawak General Hospital (CRC SGH) was established in 2003 as part of the Ministry of Health's Clinical Research Centre network (now Institute for Clinical Research, ICR). Initially providing administrative support, the centre progressively expanded its technical capabilities in clinical research. A key milestone was the conduct of the first bioequivalence (BE) study in March 2013 at its satellite site in Sarawak Heart Centre, which strengthened staff expertise in early-phase research. In November 2016, CRC SGH began operations in a new dedicated CRC building at SGH, equipped with an early-phase clinical research ward, research laboratory, and physiology laboratory.

With these facilities in place, CRC SGH embarked on its NPRA Phase 1 Unit accreditation journey in 2018. Following an NPRA inspection in March 2019, CRC SGH became the first site in Malaysia to receive provisional accreditation under the NPRA Phase 1 Unit Accreditation Programme in November 2019. This achievement paved the way for the site's first First-in-Human (FIH) study in 2023.

Hospital Ampang

Hospital Ampang's First-in-Human (FIH) journey stems from the Ministry of Health's long-term vision to build comprehensive early-phase clinical trial capacity within the public healthcare system. Strategically located in the Klang Valley, the hospital was identified early as an ideal site for early-phase studies. A dedicated ward was progressively transformed into a purpose-built Phase 1 research facility, supported by a robust quality management system and an independent Quality Assurance team. Parallel investments in human capital included specialised early-phase training overseas.

A major milestone was achieved in 2011 with a Memorandum of Agreement between the Ministry of Health and Veeda Clinical Research, leading to the first pivotal bioequivalence (BE) study in 2012. NPRA accreditation under the Bioequivalence Centre Compliance Programme followed in 2014. Capability continued to mature, with enhanced clinical pharmacology expertise and increasing study complexity, including a drug-drug interaction study in 2023 and the first First-in-Patient study in 2024. These achievements culminated in NPRA accreditation under the Phase 1 Accreditation Unit Programme, formally recognising Hospital Ampang as a public-sector site capable of conducting First-in-Human studies.

NPRA ACCREDITATION MILESTONES

Hospital Ampang

- Provisional : 11-13 Jan 2022
- Full Registration : 12 May 2024
- Focus : Phase 1 & FIH Clinical Trials

Sarawak General Hospital

- Provisional : 18 Nov 2019
- Full Registration : 18 Nov 2023
- Focus : Phase 1 & FIH Trials

FIH OPERATIONS TEAM STRUCTURE

Role/Position	Hospital Ampang	Sarawak General Hospital
Clinical Leadership	<ul style="list-style-type: none"> Principal Investigator (PI) from relevant clinical discipline 	<ul style="list-style-type: none"> Principal Investigator (PI) from relevant clinical discipline
Medical Officers	<ul style="list-style-type: none"> 2 	<ul style="list-style-type: none"> 5
Study Coordinators	<ul style="list-style-type: none"> 8 CRM study coordinators 2 clinical research wards study coordinators 	<ul style="list-style-type: none"> 31 CRM study coordinators
Research Pharmacists	<ul style="list-style-type: none"> 4 	<ul style="list-style-type: none"> 4
Research Nurses	<ul style="list-style-type: none"> 3 	<ul style="list-style-type: none"> 15
Assistant Medical Officers	<ul style="list-style-type: none"> NA 	<ul style="list-style-type: none"> 2
Quality Assurance Team	<ul style="list-style-type: none"> 2 QA Officers 	<ul style="list-style-type: none"> 1 QA manager 1 QA Executive
Total Team Size	<ul style="list-style-type: none"> 15 staff members 	<ul style="list-style-type: none"> 59 staff members

CLINICAL RESEARCH FACILITIES

HOSPITAL AMPANG

Inpatient Capacity	10 inpatient beds
Bioequivalence (BE) Ward	Dedicated 36-bed BE ward
Participant Facilities	<ul style="list-style-type: none"> • 2 screening room • 1 recreational room • 1 dry toilet
Patient Monitoring	<ul style="list-style-type: none"> • CIC Pro Clinical Information Centre • GPS synchronised clocks
Laboratory Support	<ul style="list-style-type: none"> • ULTF -20C and -80C • Refrigerated centrifuge • Bioanalytical laboratories (external collaborator)
Security	<ul style="list-style-type: none"> • CCTV surveillance • Access controlled
IP Management	<ul style="list-style-type: none"> • Dedicated pharmacy room with continuous monitoring of temperature and relative humidity and alarm system. • Pharmaceutical fridge 2-8C • UV filtered light • IP freezer -20C, and -80C
Administrative & Research Areas	Meeting rooms, monitoring spaces, research consultation clinics

SARAWAK GENERAL HOSPITAL

Inpatient Capacity	10 inpatient beds, including 2 ICU-capable beds
Bioequivalence (BE) Ward	Dedicated 24-bed BE ward (at satellite site in Sarawak Heart Centre)
Participant Facilities	<ul style="list-style-type: none"> • 1 subject recreational room • 1 counseling room
Patient Monitoring	Centralised monitoring system with synchronised clocks
Specialised Equipment	Medical equipment supporting intensive monitoring for FIH studies
Laboratory Support	Dual ISO-certified laboratory
Laboratory Accreditation	<ul style="list-style-type: none"> • MS ISO 15189:2022 • MS ISO/IEC 17025:2017
Laboratory Capabilities	Haematology, biochemistry, coagulation, molecular genetics, drug level analysis
Physiology Laboratory	Cardiac (ECHO, ECG, Holter, telemetry), pulmonary (CPET) & neurological (EEG)
IP Storage	Dedicated IP storage with continuous temperature monitoring and alarm systems (ambient & refrigerated)
Outpatient Consultation Rooms	5 rooms
Administrative & Research Areas	Meeting rooms, monitoring spaces, research consultation clinics

Metrics	Hospital Ampang	Sarawak General Hospital
<p>Total number of FIH / early phase trials conducted, with therapeutic areas indicated</p>	<p>FIH - 1 in Paroxysmal Nocturnal Hemoglobinuria (PNH)</p>	<p>FIH - 6 in oncology (solid tumor), 1 in rheumatology (Systemic Lupus Erythematosus (SLE))</p>
<p>Therapeutic areas that site can conduct for First-in-Human (FIH) studies</p>	<p>Healthy volunteer, vaccines, drug-drug interaction, food effect, haematology, medical, and other diseases</p>	<p>Oncology, rheumatology, haematology, infectious disease and cardiology</p>
<p>Number of dedicated research staff (e.g., coordinators, nurses)</p>	<ul style="list-style-type: none"> • 3 doctors • 4 pharmacists • 3 nurses • 2 study coordinators • 2 QA personnel 	<ul style="list-style-type: none"> • 5 medical officers • 4 pharmacists • 15 nurses • 31 study coordinators
<p>Key achievements or experiences (e.g., certifications, inspections passed, recruitment milestones)</p>	<ul style="list-style-type: none"> • 2024: Achieved full accreditation to be listed in the NPRA Phase 1 Unit Programme in May. • Collaborating with DNDi and Liverpool Clinical Research Facility to conduct FIH trial on novel class of therapeutic for Leishmaniasis disease. • Early Phase & Specialty Trials: Conducted First-in-Patient (FIP) trials for Paroxysmal Nocturnal Hemoglobinuria (PNH). 	<ul style="list-style-type: none"> • NPRA Phase 1 Accreditation • MS ISO 15189: 2022 Accreditation • MS ISO/IEC 17025: 2017 Accreditation • MREC inspection on FIH study in 2025 with only minor findings • Global First Recruiter in Advanced Solid Tumor (Dr Voon Pei Jye)

HOSPITAL AMPANG



BE ward area



Phase 1 ward



Recreational room



Sample storage room



Screening room



Pharmacy room



Study team on Paroxysmal Nocturnal Hemoglobinuria first-in-patient clinical trial



Discussion with DNDi and Liverpool Clinical Research Facility team on Leishmaniasis FIH trial

SARAWAK GENERAL HOSPITAL



Entrance to the research ward



Clinic consultation room



HDU bed in research ward



ICU bed in research ward



Dedicated pharmacy



Investigational Drug Service (IDS) Room



Nursing station in research ward



Physiology laboratory



ISO accredited laboratory



Meeting room at administrative area



SGH FIH team during the SIV of the first FIH with CMIC



NIPRA inspection in 2023 for full accreditation

CONTRIBUTION

Early to Late-Phase Clinical Trials in Malaysia: The OrigAMI-1 Success Story

■ Author: Keong Li-Ann, Local Trial Manager, Johnson & Johnson Sdn. Bhd.

It often starts quietly – perhaps a little fatigue, a change in bowel habit, or stomach discomfort and people blame on the food they ate last night. But sometimes, these everyday annoyance mask something far more serious – colorectal cancer. A disease that affects millions each year and often goes unnoticed until it's advanced.

Yet, hope lies in progress. Advances in treatment availability are changing the outlook for patients every day. Clinical trials give patients access to promising treatments that are not yet widely available, offering both improved outcomes and the chance to contribute to discoveries that may save future lives.

In this article, I am going to cover the introduction of OrigAMI-1 study in Malaysia and how it demonstrated the dedication and capability of the local trial sites – proving that Malaysia can be a strong contributor to global cancer research, both in quality and recruitment. OrigAMI-1 is an early-phase study targeting patients with advanced colorectal cancer and is among the first studies conducted by the company for this indication. We selected three hospitals in Malaysia to participate in this study.

Sarawak General Hospital (SGH), led by **Dr Voon Pei Jye**, was our first site to be engaged. SGH, located in the famous state of Hornbill, is one of the few hospitals in Malaysia being accredited to conduct first-in-human clinical trials. Even prior to the formal initiation of the study, we started in-depth discussion with Dr. Voon to gain a thorough understanding of the landscape of this indication in Malaysia, including existing clinical practices, patient populations, and potential logistical considerations. Dr. Voon is not only highly experienced in leading and conducting trial research but is also renowned for being a patient-centric Principal Investigator who is deeply loved by his patients. His insights are therefore invaluable to the success of this study. I remembered he told us, *"Bring the trials in, our patients are waiting"*.

As an earlier-phase trial, input from experts is crucial as the recruitment performance is under the spotlight especially for a proof-of-concept trial like OrigAmi-1. Dr Voon actively participates in the Safety Evaluation Team meetings, contributing his ideas and concerns directly to the sponsor,

which significantly influence the refinement of the protocol and study designs. To ensure optimal support, Dr. Voon has assembled the best team from his site – a special shout out to sub-investigator **Dr Kho Swee Kiong** for being the powerhouse in this study, along with the dedicated Clinical Research Malaysia study coordinators – I like to call them the **Invincible Trio, Rosierra, Ann and Cindy**, to facilitate and drive the study's success. The achievement is not just short-term. Despite having started in 2022, you can never believe that the metrics (data entry and query resolution timeline) have remained consistently green throughout the years. This is not a common sight for a fast-paced oncology study, and it truly speaks to the exceptional dedication and collaboration of the entire team.



Figure 1: Photo taken at RadioTherapy Unit, Hospital Umum Sarawak. From left to right JnJ SM Kah Fong, Cindy, Ann, Rosierra, Dr Kho and Dr Voon with the team signature posture, 'Number 1!'

And then we have **University Malaya Medical Centre**. The study was initiated by **Prof Dr Ho Gwo Fuang** and is now being carried forward by **Assoc Prof Dr Rozita Abdul Malik**. Together, they have contributed 17 patients to the study, making them the top recruiter globally – outperforming sites from larger countries like the United States, South Korea and China. This site was featured in the global study newsletter to share their success story in recruitment, which was driven by their extensive internal database, wide network of connections, and a dedicated local investigator team. But have you heard the quote *"with great power comes great responsibility"*?

Managing such a large number of patients requires exceptional dedication and seamless collaboration from the entire team to oversee patient visits, data integrity, drug accountability, and many other tasks. This site was also selected for a site audit during the year-end holidays. However, with such an incredible team, comprising of experienced Principal Investigators and dedicated study coordinators – **Madiah, Iqmal, Wei Ying, Haniesya, Alice and Durratul**, these challenges were managed so seamlessly that you wouldn't even realize there was any significant risk involved.

Beacon Hospital, led by **Dr Azura Rozila Ahmad** also contributed significantly to the study by being the first site in Malaysia (and the second globally) to recruit a patient for this study. As one of the earlier sites with patients, the team proactively addressed potential issues and unknown challenges, and shared insights with local team and other sites to improve the overall study quality.

There is a saying, ‘high risk, high return.’ We took the gamble of bringing a trial with a brand-new indication to Malaysia, without knowing where it might lead us. With the guiding statement, ‘**our patients are waiting**’, the process of recruitment, and maintaining the study quality is worthwhile, despite the various hurdles, and hiccups encountered during the trial conduct. The commitment from each site team members translated into the study's successful delivery, laying a solid foundation for subsequent, larger studies in the program – the OrigAMI-2 and -3. The dedication has positioned Malaysia to continue its participation in the program, with broader participating hospitals, further strengthening Malaysia in the global research landscape. This also translates into greater access for patients across Malaysia to innovative drugs, especially considering that the current Standard of Care in government hospitals for Colorectal Cancer is limited. This is truly remarkable and represents a significant achievement that we have been aspiring to attain as a nation!

It is truly a blessing to have dedicated Key Opinion Leaders (KOLs) in Malaysia, representing the country and helping Malaysia shine and gain recognition not only within the region, but the world. As a developing nation, building on the influence of KOLs is one of the initial steps to bring clinical trials to Malaysia. KOLs serve as important ‘messenger’ to bridge the gap between the country and the Sponsor who is sitting out of Malaysia. We truly appreciate all the KOLs in Malaysia. **You rock!** You are shaping and building a better ecosystem for conducting clinical research in Malaysia!



Figure 2: Photo taken at Clinical Oncology Unit, University Malaya Medical Centre. From left to right – Iqmal, Madiah, Assoc Prof Dr Rozita, Haniesya.



Figure 3: Photo taken at Clinical Investigational Centre, University Malaya Medical Centre, in 2023. From left to right – JnJ MCO Wei Quan, LTM Li-Ann, Prof Dr Ho, Alice.

MEET OUR TEAM



Ali Iqbal Bin Ghazali Hasni

CRM Associate Regional Manager, East Coast A

Tell us about yourself and your journey with CRM

I graduated with a Medical Degree from Crimea State Medical University in 2012. I joined the company in October 2013 as a Study Coordinator Level 1. I was promoted to Senior Study Coordinator in 2018 and became Associate Regional Manager in 2020.

As Associate Regional Manager for East Coast A, I lead and supervise teams to ensure clinical trials are conducted efficiently and with the highest quality standards. My work involves resource allocation, planning, budgeting, and overseeing trial execution across all sites in my region.

What are your key responsibilities?

My role centers on four main areas:

- **Leadership & Supervision:** I oversee Study Coordinators and Clinical Trial Administrators, ensuring compliance with SOPs, GCP, and ISO standards while monitoring trial progress and supporting recruitment efforts.
- **Staff Development:** I focus on growing our team through Individual Development Plans, training opportunities, and delegating responsibilities to build skills and prepare staff for future roles.
- **Collaboration & Improvement:** I contribute to acquiring new trials, participate in process improvements, and work with management on regional training plans and budgets.
- **Administration:** I manage leave, claims, performance appraisals, and ensure all activities align with our KRAs and KPIs.

How do you support your Study Coordinators?

I provide hands-on support through regular site visits, supervisory meetings, and coaching sessions. I encourage open communication so issues are identified and resolved early, working closely with Headquarters, Investigators, and CRC teams. Through targeted training and Individual Development Plans, I help build their competence and confidence to handle complex studies.

What challenges do you face and how do you address them?

Common challenges include competing clinical workloads, recruitment difficulties, and inconsistent adherence to timelines. I manage these by strategically redistributing workload—structuring responsibilities around one to three therapeutic areas per coordinator, each aligned with a maximum of three Principal Investigators. This focused approach reduces fragmentation and improves efficiency despite heavy clinical demands.

What's been most rewarding about your work?

Seeing our team grow from just 2 Study Coordinators at HRPZ II and 1 at HSNZ when I started in 2013, to 7 and 3 respectively today, has been incredibly rewarding. Equally fulfilling is watching team members advance their careers by joining Sponsors and CROs. Most satisfying is seeing patients successfully complete their trial journeys, knowing our work contributes to advancing medical science while supporting their care.



Standing from L-R: Abdullah, Mohamad Darwish, Ali Iqbal, Nur Azriena, Nora Diana, Siti Fauziah, Emmilia, Wan Nooremira, Nurul Suhaili Amirah, Nur Aina, Maisarah

Muhammad Amin Hafiz Bin Soozaimi

HR Specialist, CRM

Sports & Recreational Committee – Creativity in Virtual SRC Activities – CEO Award 2021 (Team Category)



How has your role at CRM changed over the years, and what keeps you excited about it?

I joined CRM in July 2018 as a Human Resources Assistant with a Diploma in Business Studies. It was a six-month contract before progressing to Human Resources Executive, then Senior Human Resources Executive and in 2025 promoted to Human Resources Specialist.

Almost eight years working for Clinical Research Malaysia, I have grown with the organization, pursuing a part-time Bachelor of Business Administration (Hons.) in Human Resources Management at UiTM, which I completed in September 2025.

My role focuses on operational and administrative Human Resources functions, particularly talent acquisition and learning and development, while ensuring compliance with ISO 9001:2015 Quality Management System (QMS) and ISO 37001:2016 Anti-Bribery Management System (ABMS) requirements.

What excites me are the people. While procedures remain structured, every candidate brings different perspectives. The challenges—and satisfaction—lies in identifying the right person for the right role at the right time, aligned with CRM Core Values, technical requirements and fitness to its culture and overall organization standards.

How do you figure out what training or development staff need most, and what's your approach to supporting their growth?

Employees' learning and development needs can be traced back to performance reviews mid-year and year end, feedback by line managers, head of departments, customer satisfaction surveys, observations and coaching sessions. The needs to grow do not necessarily undergo formal training programs. They can be as simple as stretched assignments, inter-departmental projects, committee related activities and many more in line with 70-20-10 principles.

In supporting the employees' growth, I ensure the organized programs meet their objectives in developing and equipping employees with identified necessary competencies to bring up work performance to greater heights.

In your day-to-day, how does HR help teams work smoothly together across the organization?

We prioritize activities that bring significant impacts to the company's objectives, KPIs and targeted goals. Simultaneously, we ensure harmonious working environment through clear communication and expectation with high collaboration among employees.

What has been the most rewarding or memorable part of your HR journey so far?

Seeing the impact of good hiring decisions. During annual events and conferences, hearing the new joiners share their experiences at CRM is a reminder of how meaningful the work behind recruitment can be.

How do you usually start your day at CRM, and do you have any routines that help you stay on top of everything?

I would stay on top of everything when clear directions, targeted goals, management support and guidance are readily available. Highly focused mindset, enough rest and a proper breakfast would make my day. I call this a good start to the day.



Standing from L-R: Anis, Puan Zaleha, Norazua & Amin

CRM IN PHOTOS



Wrapped up the final touch base with MSD for 2025

4
Sep



CRM met with Nexsen and Biogenes team

11
Sep



Engagement with the IQVIA and AMGEN team

11
Sep



Meeting with Mr Kunihiro Nishimura, CEO of Xcoo

19
Sep



Meeting with Boehringer Ingelheim

25
Sep



Engagement with Mr Jummat Huang, Chief Representative for Malaysia from Innovita

30
Sep



CRM visits Siriraj Institute of Clinical Research (SICRES) in Bangkok

3
Oct



Meeting with Zero Range Healthcare

30
Oct



Meeting with Parexel team

31
Oct



Meeting with AbbVie team

10
Nov



Meeting with NCSM & ECHO Project

13
Nov



Meeting with SIRIM Life Sciences team

21
Nov

CRM IN PHOTOS



Meeting with Mr. Arieff Aaron Abdullah, Director of the Selangor Biotechnology Coordination Office (S-BIOCO), and Ms. Faraheen, Executive at S-BIOCO

8
Dec



Zerorange Healthcare team met with CRM

12
Dec



Touch base meeting with Regeneron.

19
Dec



Difficulty in patient recruitment?

CRM Clinical Trial Advertisement Service

addresses your needs



Sponsored Ads



Facebook & Instagram Platforms



Targeted Audience



Complimentary Ad Design



Ad Performance Report Provided



Flexi Package Duration



Ensure data integrity in clinical trials with

CRM Study Material Destruction Service



Comply with Standard Operating Procedures, Good Clinical Practice & NPRA Guidelines



CRM Provides Certificate of Destruction



Certified Destruction through Qualified Vendor with ISO 9001:2015, ISO 14001:2015 & ISO 45001:2018

NPRA, National Pharmaceutical Regulatory Agency, ISO 9001:2015, Quality Management System, ISO 14001:2015, Environmental Management Systems, ISO 45001:2018, Occupational Health and Safety Management System

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