

CRM Bulletin

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**REFLECTING ON ACHIEVEMENTS,
EMBRACING NEW HORIZONS**

**RISING STARS IN
ENDOCRINOLOGY**

**FEATURED SITE:
SULTAN IDRIS SHAH
HOSPITAL, SERDANG**



RESEARCH PERSONALITY

Dr Suhana Yusak



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 CRM Bulletin 29.

Happy New Year, dear reader!

Welcome to 2025, a year brimming with fresh opportunities while staying rooted in our core principles of Humanity, Stability & Sustainability. Before diving into the adventures and aspirations of the new year, let us take a moment to reflect on the milestones that shaped the final months of 2024.

From August to December 2024, the pace of progress was remarkable with impactful moments that propelled CRM closer to its mission. We closed the year with our 3rd Board of Directors meeting, featuring insightful discussions and strategic directions. The final months also saw a flurry of international engagements, strengthened collaborations and successful hosted events. Notably, we celebrated the forging of a new partnership with BeiGene, a global pharmaceutical company, marking a significant step in advancing our research capabilities.

In this Bulletin, you'll journey through these highlights and more. Discover the inspiring work of one of our renowned Principal Investigators in Research Personality section, highlights, insightful engagements and explore the featured site & gain insights into the collective achievements that wrapped 2024 on a high note. Let's reminisce and celebrate together as we embark on an exciting new chapter.

Dr. Akhmal Yusof
CEO, Clinical Research Malaysia

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2033

VISION

To be the preferred hub
for clinical research in Asia

MISSION



Global Trusted Research
Management Organisation



Clinical Research
Professions Development



Digitalise
Processes



KPI
2023 – 2033

HIGHLIGHTS



Regional Asian Clinical Trial Association (REACTA) 2024

1-3 August 2024 – CRM participated in REACTA 2024 at Taipei Medical University, engaging with member organisations, speakers, and delegates. As a board member, CRM shared insights on Malaysia's Local Care Model, a DCT approach, under the theme 'From Ideation and Validation: Clinical Trials in the Digital Era'.



American Society of Clinical Oncology (ASCO) Breakthrough 2024

9 August 2024 – CRM and Dr Ros Suzanna (MOH) met Prof Lilian Siu (Princess Margaret Cancer Centre) during the ASCO Breakthrough program in Japan, to discuss collaborations with CRM, MOH and UMMC, including on early-phase partnerships. Also participating in the conference was Dr Lim Yueh Ni (SGH) who was under the ASCO Leadership Program, and Dr Davi Lee (UMMC) who presented on hippocampus-sparing whole-brain radiotherapy.



Bioweeek China 2024

8-10 August 2024 – At Bioweeek China's Global Clinical Development track, CRM showcased Malaysia's clinical trial landscape with NPRA discussing regulations and BeiGene sharing insights on expanding trials in Southeast Asia. A close dialogue also connected China-based biotechs with CRM and NPRA to discuss trial planning in Malaysia.



A Glimpse into Drug Development

9 & 22 August 2024 – CRM hosted a hybrid CME featuring Dr Albiruni Razak from Princess Margaret Cancer Centre, who shared insights on early oncology drug development. He also engaged UMMC's oncology team, offering guidance on Phase 1 setups as they pursue FIH accreditation, further boosting Malaysia's clinical trial potential.



2nd Protocol Compliance Workshop of 2024

14 August 2024 – CRM held its 2nd Virtual Protocol Compliance Workshop of 2024, featuring invaluable insights from Dr Lee Keng Yee (MREC) and Mr Rattapol Holasut (IQVIA). Through the workshop, the attendees gained essential knowledge to enhance their clinical tasks and compliance practices.



12th National Pharmacy R&D Conference 2024

19-21 August 2024 – CRM CEO Dr. Akhmal Yusof gave a strong speech on medicine security, stressing the importance of robust clinical trials. He highlighted CRM's work in building a trusted research ecosystem, from Phase 1 to Phase 4 studies, and training future talent through the Centre of Excellence program. With CRM Vision 2033, the organization continues to lead in research and innovation.



Breaking Barriers: A Clinical Trial Participant's Story

21 August 2024 – CRM hosted an insightful interview with Geraldine Tong from The Sunday Star, the journalist behind the article 'The Rise of Clinical Research.' During the interview Mr Syed Johari, a clinical trial participant with idiopathic pulmonary fibrosis, shared his inspiring journey and experiences.



MREC Good Submission Practice Workshop

22 August 2024 – CRM hosted the MREC Good Submission Practice Workshop, uniting key stakeholders in ethics submissions for sponsored research. Special thanks to Dr. Lee Keng Yee (MREC), Ms. Kasturi (NMRR), and Ms. Mah Kar Yee (MREC) for their invaluable insights.



Empowering Future Clinical Researchers

19-23 August 2024 – 16 Provisionally Registered Pharmacists (PRPs) have successfully completed CRM's Clinical Research module, gaining insights into Malaysia's clinical research landscape, Good Clinical Practice and the important role study coordinators play in supporting clinical trials. We look forward to seeing them thrive in their clinical research careers and contribute to the continued growth of the industry.



Celebrating 25 Years of Excellence: UMMC CIC's Milestone in Clinical Research

23 August 2024 – University of Malaya Medical Centre Clinical Investigation Centre (UMMC CIC) celebrated its 25th anniversary, marking a milestone as Malaysia's top contributor to sponsored clinical research. With its commitment to advancing medical science through clinical trials, UMMC CIC has earned recognition as the nation's leading study site. CRM congratulates UMMC CIC on its remarkable achievements and looks forward to many more successes in the years ahead.



5th I AM AWARE Roadshow

26 August 2024 - In collaboration with Sunway Medical Centre Clinical Research Centre, CRM successfully held its 5th I AM AWARE roadshow to raise public awareness of clinical trials. This event offered an engaging platform to educate the public on the importance of clinical trials in advancing medical science, ensuring treatment safety and effectiveness, and ultimately enhancing patient care.



FARO-ESTRO Congress @ ESTRO Asia Meets 2024

27 August 2024 - CRM participated in the FARO-ESTRO Congress 2024, enhancing collaboration in radiation oncology between Europe and Asia. Malaysian oncologists, Assoc. Prof Dr Marniza Saad and Dr David Lee, shared insights on prostate cancer and nasopharyngeal carcinoma. Dr Lee's abstract was selected for the FARO Travel Grant Award, highlighting Malaysia's growing role in oncology research.



East Coast Research Day

27 August 2024 - CRM participated in the 2nd East Coast Research Day at The Grand Renai Hotel, Kota Bharu, officiated by Dato' Dr Nor Fariza Ngah, Deputy Director General (Research and Technical Support). CEO Dr Akhmal Yusof shared insights on Malaysia's clinical research progress and future directions. The event highlighted the health white paper on research strategies, and Dr Fariz Safhan discussed how ISR has advanced therapeutic options for managing chronic kidney disease.



International Symposium for Asia Regulatory Coordination

29 August 2024 - CRM participated in the International Symposium for Asia Regulatory Coordination in Bangkok, marking the launch of PMDA's first international base. As a panel member, CRM discussed the growth of clinical trials in Asia, emphasizing Malaysia's expanding clinical trial capacity.

The event featured opening remarks from the Ministers of Health of Japan and Thailand, followed by a keynote from PMDA's CEO. The symposium focused on regional collaboration, regulatory harmonization, and advancing clinical trial innovation. CEO Dr Akhmal Yusof represented CRM, sharing Malaysia's vision for clinical research development.



Malaysia Thoracic Society Annual Congress 2024

31 August 2024 - During this annual congress, CRM CEO Dr Akhmal Yusof emphasised the crucial role of pulmonologists and chest physicians in respiratory and lung cancer clinical trials. With Malaysia having conducted 14 respiratory and 17 lung cancer studies in 2023, the congress provided a valuable platform for networking and collaboration with experts and researchers.



Public Symposium on Emerging Issues in Research Ethics

11 September 2024 - CRM joined the public symposium co-hosted by the Faculty of Medicine, Universiti Malaya and the Berman Institute of Bioethics, Johns Hopkins University. The event featured three world-renowned experts discussing research ethics in medical AI development and advancing justice and equity in clinical trials.



ESMO Congress 2024

13-17 September 2024 - During the ESMO 2024 in Barcelona, CRM along with Dr Ros Suzanna (Head of Oncology & Radiotherapy Service) had productive engagements with several industry leaders including those in AstraZeneca, Johnson & Johnson, Merck & Co, Gilead, Oric Pharmaceuticals & Nuvalent. CRM also hosted a Malaysian diaspora gathering, uniting 11 clinicians from the UK, Canada, Ireland, and Malaysia to reconnect and explore future collaborations.



CRM Strengthens Partnership with Princess Margaret Cancer Center at World Cancer Congress

19 September 2024 - At the World Cancer Congress in Geneva, Malaysia's Health Minister and his team, along with Dr Ros Suzanna and CRM met with Dr. Keith Stewart, Director of the Princess Margaret Cancer Center. Since formalizing their partnership in 2022, PMCC have been a significant collaborator in enhancing Malaysia's early-phase cancer capabilities. This meeting strengthens their collaboration and paves the way for future initiatives together in the oncology landscape.



CRM Congratulates UMMC on Silver Jubilee Celebration

19 September 2024 - CRM visited Dr Yeoh Wei Sien to congratulate him on his appointment as Head of CIC and presented a plaque to him and the CIC team in celebration of their silver jubilee. The visit reaffirmed the strong collaboration between CRM and UMMC, especially in co-chairing the REACTA forum during CRM Trial Connect 2025.



Nurturing New Talents in Sponsored Research

24 September 2024 - CRM successfully held its first interactive forum session during its NNT seminar at Melaka Hospital. Special thanks to panelists Dr. Shalini Vijayasingham, Head of CRC at Hospital Melaka, and Mr. Samiran Maity, Head of Clinical Development Centre at Novo Nordisk Pharma Malaysia, for sharing valuable insights.



CRM Visits Northern Region to Boost Clinical Research

26 September 2024 – CRM CEO, Dr. Akhmal Yusof, visited the Northern Region, meeting Dr Mohd Azri, Head of CRC Sultanah Bahiyah Hospital, and Dr Arvindran Alaga, Head of Respiratory. The visit included an on-site PDPA training session and discussions on advancing Industry-Sponsored and Investigator-Initiated Research at CRC HSB and CHEST Alor Star. It was inspiring to see young doctors and study coordinators collaborating as future leaders in Kedah's clinical research.



13th Sarawak Research Day

30 September 2024 – CRM sponsored and attended the 13th Sarawak Research Day at Promenade Hotel, Bintulu, officiated by Dr. Melvin Chung Hsien Liang, Head of Bintulu Divisional Health Office. With the theme 'Discover, Innovate, Inspire,' the event encouraged clinicians to pursue careers in clinical research. CRM also set up a booth to engage with clinicians interested in starting their journey in clinical research.



Centre of Excellence 2024

27 September & 13 December 2024 – CRM successfully completed 2nd and 3rd batches of its Foundation Program for Study Coordinators in 2024. The 12 week training program provided participants with a comprehensive understanding of clinical trial support, combining theoretical learning with practical experiences. The program equipped them with the essential skills to contribute effectively to clinical research. CRM extends its gratitude to all trainers and instructors for their invaluable contributions and looks forward to the positive impact these professionals will bring to the clinical research field.



Celebrating the Launch of the New CRM-CRC Office and Advancing Oncology Research

4 October 2024 – CRM launched its newly renovated CRM-CRC office at Hospital Raja Permaisuri Bainun (HRPB) during the Perak Annual Medical Research Conference 2024. The new office will support the growth of sponsored research and clinical trials, particularly in oncology. HRPB is now also an ATLAS site for the National Cancer Center of Japan, expanding access to innovative therapies for patients in the Northern Region.



CRM Hosts Delegates From Japan to Enhance Research Collaborations

7 October 2024 – At CRM hosted delegates from Kyushu University Hospital, NCGM, and CMIC to enhance research collaboration between Japan and Malaysia! The visit included discussions on Decentralized Clinical Trials (DCTs) and insights into the Local Care Model, followed by a tour of CIC UMMC and Sultan Idris Shah Hospital. CRM is grateful for these valuable exchanges and looks forward to further collaboration in advancing clinical research.



Strengthening Clinical Research Collaboration

10 October 2024 – CRM had the honor of briefing Dato' Sri Suriani binti Dato' Ahmad, Secretary General of the Ministry of Health Malaysia, on CRM's mission to enhance the clinical research ecosystem in Malaysia through Speed, Quality, and Reliability. As a Global Trusted Research Management Organisation, CRM is committed to the principles of Humanity, Stability, and Sustainability. CRM appreciates Dato' Sri Suriani's support and interest in advancing clinical research.



Hospital Sungai Buloh Researchers' Appreciation Day

10 October 2024 – CRM participated in the Hospital Sungai Buloh Researchers' Appreciation Day, officiated by Dr Jasmeet Singh Sucha Singh, Director of Hospital Sungai Buloh. At the event, CRM's Senior Feasibility Specialist, Ms Cheng Shu Hui, shared insights on feasibility approaches for industry-sponsored research. CRM also hosted an engagement booth, connecting with clinicians keen on exploring clinical research opportunities.



Shah Alam Hospital's Research Awareness

11 October 2024 – Shah Alam Hospital's Research Awareness Week kicked off in the 2nd week of October with CME sessions, exhibitions, poster presentations & quizzes. CRM's Senior Business Development Manager, Ms Asha Thanabalan, was among the CME speakers, sharing insights on Industry-Sponsored Research. CRM also hosted its 6th I AM AWARE roadshow to boost public awareness of clinical trials. Dr Akhmal Yusof, CRM's CEO, attended the closing ceremony to support this significant initiative.



35th Annual Scientific Congress of Malaysian Oncological Society

11-13 October 2024 – CRM participated in ASCOSMOS 2024, showcasing innovations in oncology research and exploring the evolving landscape of cancer treatment. Discussions featured case studies & updates on oncology care, emphasising growing opportunities for clinical trials. CRM is proud to contribute to this transformative event, fostering collaboration and advancing oncology research.



Pink October Carnival 2024

14-18 October 2024 – In support of breast cancer awareness, CRM participated in the Pink October Carnival 2024 at Kuala Lumpur Hospital. As part of the event, CRM organised its 7th I AM AWARE campaign to raise awareness about clinical trials and encourage healthcare professionals to join industry-sponsored research. These efforts reflect CRM's commitment to advancing research for better outcomes for breast cancer patients.



'Promoting Integrative Medicine' Workshop

16 October 2024 – CRM joined the 'Promoting Integrative Medicine' workshop, organised by the TCM Division of the Ministry of Health to explore opportunities for integrating TCM into patient care. The event highlighted the importance of research in supporting evidence-based TCM during a dialogue with the DG of Health, Datuk Dr Radzi bin Abu Hassan, and panelists Prof Dr Abdul Rashid bin Abdul Rahman (CRM Board Member) and Dr Goh Cheng Soon (Director of TCM Division).



Good Clinical Practice Refresher (GCPR) Workshop

16 October 2024 – CRM successfully conducted its third virtual GCP Refresher Workshop for 2024, facilitated by Ms Young Kai Shen. The workshop provided attendees with updated knowledge and essential insights into Good Clinical Practice, reinforcing their expertise in clinical trial conduct.



National Conference of Academic Medical Centres 2024

16-18 October 2024 – CRM attended the National Conference of Academic Medical Centres, themed "Navigating the Path to Research Excellence in Teaching Hospitals," highlighting university hospitals' role in clinical trials and fostering discussions with key research stakeholders.



Selangor Research Day & Research Awareness week

23 October 2024 – CRM participated as speakers at the Pre-Conference Selangor Research Day & Research awareness week at Hospital Shah Alam, offering a comprehensive overview of Malaysia's clinical trial landscape and CRM's role in supporting industry-sponsored research.



Patient Recruitment & Retention Workshop

23 October 2024 – CRM's Clinical Operations team have successfully conducted its 3rd Patient Recruitment & Retention workshop in 2024 with a total of 22 participants from internal and external stakeholders.



Malaysia International Healthcare (MIH) Megatrends 2024

25-27 October 2024 – CRM had the privilege in participating at MIH 2024 that was officially launched by His Majesty Sultan Ibrahim at the Kuala Lumpur Convention Centre. This event, organised by the MOH with KPJ Healthcare and MCMC, focused on AI, digital healthcare, and precision medicine. Under the MOH Pavilion, CRM highlighted Malaysia's strengths as a clinical trial hub. We're grateful for the valuable connections and insights gained to enhance healthcare for Malaysians.



ICN Annual General Meeting at Kyoto University

31 October 2024 – CRM joined the ICN Annual General Meeting at Kyoto University, where members of the International Clinical Trial Center Network (ICN) exchanged valuable strategies and initiatives in clinical trial management. As a newly inducted ICN member, CRM had the privilege of presenting on Malaysia's Study Coordinator Management practices. We extend our thanks to the ICN committee for organising such an insightful and well-structured meeting.



MACGT Annual Symposium

2 November 2024 - CCRM proudly participated as both delegates and exhibitors at the MACGT Symposium, a prestigious event that brought together experts and industry leaders to discuss the challenges and opportunities in the field of cell and gene therapies in Malaysia. The symposium emphasized Malaysia's growing contributions to advancing these cutting-edge therapies, providing a platform for in-depth discussions, valuable insights, and meaningful collaborations aimed at improving patient outcomes and strengthening the healthcare system.



Network of Ethical Review Committees in Malaysia (NERCIM)

5 November 2024 - CRM, in collaboration with MREC, co-organized the Network of Ethical Review Committees in Malaysia (NERCIM) meeting. This productive session brought together representatives from Institutional Review Boards (IRBs) of universities, private institutions, and MREC. The discussions centered on harmonizing standard operating procedures (SOPs), elevating ethical standards in clinical research, and streamlining processes to enhance efficiency and reduce review timelines.



CRM Celebrates Milestones in Phase 1 Realisation Project 2.0

12-13 November 2024 - CRM celebrated key milestones under its Phase 1 Realisation Program 2.0. Sponsored by this initiative, two NPRA officers, Ms. Fatin Diyana and Ms. Siti Norhayani, completed their Master's in Clinical Pharmacology at King's College London with distinction.

Additionally, CRM Study Coordinators Felicia (Sarawak General Hospital) and Nabila Azirah (Hospital Ampang) are currently undergoing a 3-month attachment at National University Hospital Singapore, while Ngu Lin Hui and Nur Haziqah (Sarawak General Hospital) completed a 1-week observership at National Taiwan University Hospital. These programs are designed to enhance early-phase skills and development within CRM's site operations team.



CRM Achieves ISO Recertification with Zero Non-Conformities!

13-14 November 2024 – CRM successfully underwent its recertification audit for both the ISO QMS and ISO ABMS, with ZERO non-conformity findings! This achievement not only ensures the renewal of our certifications but also reaffirms that our operations and strategic planning are on the right track. Moving forward, we are committed to maintaining continuous improvements to further enhance the delivery of clinical research services.



Partners in Success: Strengthening SC-CRA Relationships

15 November 2024 – A strong partnership between Study Coordinators (SC) and Clinical Research Associates (CRAs) plays a pivotal role in the success of clinical trials. To highlight the importance of this collaboration, CRM Study Coordinators Salwani & Hidayati were invited to share their insights on improving SC-CRA relationships at one of IQVIA's monthly Clinical Operations meetings.



PhAMA Career Day 2024

18 November 2024 – CRM was honoured to participate in the PhAMA Career Day 2024, where we shared insights into the clinical research field and engaged with delegates. The event served as an excellent platform to inspire the next generation of professionals and exchange ideas, contributing to the advancement of healthcare.



NPRA Good Submission Practice Workshop

20 November 2024 – CRM, in collaboration with NPRA, successfully concluded its 2nd CTIL/CTX Good Submission Practice Workshop for 2024 at the CRM Centre of Excellence. First launched in 2021, this workshop aimed to provide insights on preparing CTIL and CTX submissions, particularly for First-in-Human (FIH) clinical trials. The session included group activities, case study discussions, and facilitated knowledge sharing, engaging 27 industry professionals. This initiative continues to enhance clinical trial capabilities and regulatory compliance in Malaysia.



Nurturing New Talents (NNT) in Sponsored Research

21 November 2024 - CRM organized the NNT in Sponsored Research session at Tengku Ampuan Afzan Hospital, Kuantan, featuring Dr. Ahlam Naila binti Kori and Ms. Jenny Chen. The session aimed to guide attendees in becoming investigators in sponsored clinical research.



3rd ARISE Annual Meeting

21 & 22 November 2024 - CRM participated in the 3rd ARISE Annual Meeting at Siriraj Hospital, Mahidol University, discussing vaccine trials for pandemic preparedness. CRM shared updates on Malaysia's trials and explored cross-border collaboration to speed up study implementation during pandemics.



ESMO Asia Annual Congress 2024

6-8 December 2024 - CRM showcased Malaysia's strengths at ESMO Asia 2024 in Singapore, joining over 60 Malaysian oncology delegates from MOH, academic, and private centers. The event highlighted Malaysia's contributions through faculty participation and presentations while fostering collaborations to advance oncology research.



Raising Awareness on Clinical Trials with CORUM

3 December 2024 - CRM collaborated with the Colorectal Cancer Survivorship Society Malaysia (CORUM) to host a live session on clinical trials, streamed on CORUM's Facebook page. The session featured insights from Prof Dr Ho Gwo Fuang, Clinical Oncologist and Ms Staci Tan, a Clinical Trial Participant, aiming to engage the public and foster greater understanding of clinical research.



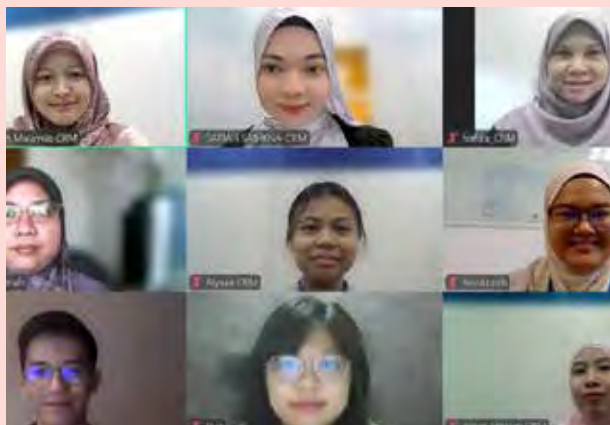
Virtual Workshop on Regulatory Inspection Preparedness

10 December 2024 - CRM held its 2nd Virtual Preparation for Regulatory Inspection at a Trial Site Workshop, led by NPRA experts Mr. Oh Chen Wei, Mr. Ahmad Izwan, and Ms. Jacinda Khoo. The session offered key insights to investigators and research teams, reinforcing best practices for regulatory compliance.



International Medical Device Exhibition & Conference (IMDEC 2024)

10-12 December 2024 - CRM participated as a strategic partner, delegate, and exhibitor at IMDEC 2024, held at KLCC. Organized by the Medical Device Authority with the Ministry of Health and the 28th Global Harmonization Working Party, the event was officiated by YB Datuk Seri Dr. Dzulkefly Ahmad, Minister of Health. The conference united global stakeholders in the medical device and healthcare sectors, showcasing innovations and fostering collaboration to advance digital health and support Malaysia's progress in the field.



Patient Recruitment & Retention Workshop

11 December 2024 – CRM's Clinical Operations team successfully conducted its 4th Patient Recruitment & Retention workshop of 2024. The workshop saw participation from 21 individuals, representing both internal and external stakeholders. This session aimed to provide valuable insights and strategies for enhancing patient recruitment and retention in clinical trials, benefiting all attendees.



Faculty of Medicine and Health Sciences Research, Innovation & Networking Week 2024

12 December 2024 – CRM participated in the FMHS Research, Innovation & Networking Week 2024 at Universiti Putra Malaysia. Officiated by Prof Dr Rukman Awang Hamat, Deputy Dean of Research & Internationalisation, the event highlighted UPM's efforts in advancing clinical research. CRM's Senior Feasibility Specialist, Ms Cheng Shu Hui presented on the essential of feasibility study conduct and the crucial to complete feasibility within the timeline.



CME Session on Lung Cancer by Dr Arvindran Alaga

19 December 2024 – Dr Arvindran Alaga, Consultant Respiratory Physician at Hospital Sultanah Bahiyah conducted a CME session for CRM Study Coordinators, focusing on the clinical aspects of lung cancer and ongoing trials. The session provided valuable insights from a principal investigator's perspective, emphasizing the importance of building a knowledgeable and skilled study team for effective trial execution.



Sarawak General Hospital Recognised for Origami-1 Study Excellence

24 December 2024 – Sarawak General Hospital was recognised for its outstanding performance in the global Origami-1 study, an early-phase colorectal cancer trial. The site excelled in query resolution timelines and data entry, surpassing other global sites despite the trial's complexity and large participant pool. This achievement is especially significant as the study has been running since 2022 and continues to exceed expectations.

SPOTLIGHT FEATURE

Malaysians Creating Waves at International Oncology Congress



Barcelona, 13 September 2024 - Professor Dr Serena Nik-Zainal, a Malaysian Scientist who is based in the United Kingdom has received the prestigious ESMO Award for Translational Research during the Opening Ceremony at the European Society of Medical Oncology (ESMO) Congress 2024 held recently in Barcelona, Spain.

The award is presented to candidates who are internationally recognized for outstanding achievements in translational research, and Prof Serena has become the first Malaysian to receive the said award. Prof Serena is being recognized for her outstanding research in the field of mutational signatures and her efforts to accelerate the translation of mutational signatures into the clinical domain. Prof Serena is a Professor of Genomic Medicine and Bioinformatics, and Honorary Consultant in Clinical Genetics at the University of Cambridge, UK. At the NIHR Cambridge Biomedical Research Centre, she leads the Genomic Medicine theme, advancing the whole cancer genomics field through computational and experimental approaches to ultimately create clinical applications.

Other noteworthy achievements by fellow Malaysians include co-authorship of a metastatic colorectal study by Dr Voon Pei Jye (Medical Oncologist at Sarawak General Hospital) and Prof Ho Gwo Fuang (Clinical Oncologist formerly at University Malaya Medical Centre) that was presented as an oral presentation. Dr Voon also co-authored a First-in-Human trial for a lung cancer study (ARTEMIDE-01) as well as became the first author for another early phase lung cancer trial (PolyDamas) that was presented at the 2024 World Conference on Lung Cancer (WCLC) that was held in San Diego from September 7 – 10. These authorships further cemented Malaysia's capability and achievements in early phase drug development. There were also other clinical trials involving Malaysian oncologists that were presented during the oral presentation sessions at the WCLC 2024.

Oncology research has been the focus of research and development of international pharmaceutical and biotech companies, recording the highest expansion rate yearly. In Malaysia, approximately 20 per cent of over 2000 sponsored research conducted are in oncology and Clinical Research Malaysia (CRM), an enabler and facilitator of sponsored clinical research for the country, strives to bring in more of such studies through its presence at the ESMO 2024. With CRM's guiding principle of Humanity, opportunities are created for cancer patients in local hospitals to access emerging trial therapies of novel checkpoints through participation in clinical trials.

Sarawak General Hospital Making its Mark in Global Early Phase Clinical Research



Kuching, 10 October 2024 - Sarawak General Hospital (SGH), together with its Clinical Research Centre (CRC) celebrated a series of significant milestones in early phase clinical research, positioning itself as a key player in the global First-in-Human (FIH) clinical trial landscape. These achievements highlighted SGH's growing reputation as a regional contender in early phase research and its excellent delivery of international sponsored studies.

Among the most recent accomplishments was the successful enrolment of the first patient in the Asia Pacific region for a new treatment in Systemic Lupus Erythematosus (SLE), an autoimmune condition that affects joints, skin, brain, lungs, kidneys, and blood vessels. The industry-sponsored FIH clinical trial was led by SGH's Consultant Rheumatologist, Dr Teh Cheng Lay.

Sarawak General Hospital was the first centre in Malaysia to have conducted a FIH clinical trial. In 2023, SGH conducted a first-in-class FIH clinical trial for patients with advanced solid tumours, led by Dr Voon Pei Jye, Consultant Medical Oncologist. Findings from this study were featured in the AACR-NCI-EORTC International Conference at Boston whereby Dr Voon became the first Malaysian to co-author a FIH global multicentre clinical trial, placing Malaysia alongside world top-ranking cancer institutes. Subsequently, a groundbreaking FIH study for advanced solid tumours was conducted, again led by Dr Voon. The study marked a historic moment earlier this July, having successfully enrolled the first patient in Malaysia.

Sarawak General Hospital's early phase accomplishments began as early as 2021, with its Consultant Haematologist, Dr Chew Lee Ping being named the first Global Recruiter for a First-in-Patient study. Since then, the nation's early phase clinical research capabilities have been running strong. Much of this is owed through Clinical Research Malaysia's Phase 1 Realisation Project which enabled the nation's early phase ecosystem from the establishment of guidelines to human capability development, as well as the establishment of the Phase 1 facility in CRC SGH.

Three more upcoming FIH oncology studies from global multinational pharmaceuticals are slated for SGH, focused on treatments for solid tumours, non-small cell lung cancer and prostate cancer. With many accomplishments under its belt, Sarawak General Hospital remains to be among the nation's top clinical research site that have significantly contributed to the global advancement of therapeutics.

Malaysia Taking the Leadership Role in ASEAN to Drive Prosperity in Industry Sponsored Clinical Trials



Kuala Lumpur, 13 December 2024 - Clinical Research Malaysia (CRM) has reached a significant milestone with the opening of its site operations office in Kuala Lumpur Hospital (HKL). This adds to CRM's growing network of satellite entities, which includes its establishments at Sarawak General Hospital and Raja Permaisuri Bainun Hospital in Ipoh as well as CRM Centre of Excellence that was launched earlier this year. The addition of these new offices is to accommodate the expansion of CRM workforce in supporting the rising demand of clinical trials in Malaysia.

The inauguration of CRM's HKL office took place immediately following CRM's Board of Directors meeting, and was officiated by YB Datuk Seri Dr Dzulkefly Ahmad, Malaysia's Minister of Health and Chairman of CRM's Board of Directors. On the day of the event, the Minister of Health also witnessed the signing of memorandum of understanding (MoU) between CRM and BeiGene, a global science-driven oncology company. The formalized partnership sets the stage for continued collaboration in enhancing the nation's clinical research ecosystem through capability development, especially in advancing clinical trial activities in Malaysia.

"As we review CRM's and the nation's clinical research performance, it is noteworthy to highlight that five new First-in-Human (FIH) trials were received in Malaysia this year, recording the highest number of FIH studies ever received," said YB Datuk Seri Dr Dzulkefly Ahmad. "This achievement further highlights the capability, quality, and standards of clinical trial conduct in Malaysia and further advances the nation's position as a leading clinical research hub in the region."

As of November 2024, Malaysia has recorded 239 sponsored clinical research for the year, contributing to over RM 330 million in Gross National Income in 2024, and close to RM 1.5 billion cumulatively since 2012. Almost a third of these trials are in cancer which brings in better and new innovative therapeutics for patients in Malaysia. In addition, the performance of Malaysia study teams in these global studies have been recognized with accolades of being top enrollers in the region and globally as well, all contributing to the reliability of the nation in delivering global studies. This has also translated to the outcome of global studies, with Malaysian clinical researchers being named as authors in over 30 high-impact publications this year.

As CRM looks ahead, it remains steadfast to continuing its mission in strengthening Malaysia's position as a leader in clinical research. The organization is currently spearheading an ASEAN-level initiative to drive prosperity to the Southeast Asia region through Industry Sponsored Clinical Trials (ISCT) and aims to further strengthen the region's foothold for the conduct of these global trials.

RESEARCH PERSONALITY



About Dr Suhana Yusak

Dr Suhana binti Yusak is an accomplished clinician and researcher with over eight years of experience in clinical trials and medical research. Her work focuses on improving the lives of patients with breast cancer, non-small cell lung cancer, and melanoma. As a Principal Investigator, she has led impactful studies exploring innovative therapies, always striving to deliver hope and better outcomes for patients.

Dr Suhana has had the privilege of collaborating with renowned research organisations both nationally and internationally, contributing to the development of life-changing treatments. She is equally passionate about mentoring aspiring researchers, sharing her knowledge to inspire patient-focused and meaningful scientific progress. Her findings have been widely published in respected journals, and she is frequently invited to share her expertise at major conferences. At the heart of her work is a deep commitment to making a difference—whether by driving therapeutic advancements, upholding ethical standards, or ensuring that every step of research is grounded in compassion and patient care.

Could you share with us the beginning of your journey as a principal investigator and the challenges you encountered?

My journey as a Principal Investigator began with a prostate cancer clinical trial, during which Clinical Research Malaysia (CRM) provided the essential resources to manage the study effectively. The opportunity to make a meaningful impact on patient care beyond standard practice was motivating. With the support of the research team, I successfully navigated my first trial, gaining valuable insights into patient recruitment, ethics and data management.

As I took on more complex studies, CRM's support for investigator-initiated trials has been invaluable. One significant challenge was recruiting patients for a trial with strict inclusion criteria. It was an oncology study with a slow recruitment pace initially. By collaborating with other hospitals and using technology to streamline screening, we significantly improved recruitment and completed the study on time.

These experiences continue to fuel my commitment to advancing clinical research and improving patient outcomes.

What drives you to conduct clinical trials?

What drives me is the opportunity to make a tangible & positive impact on patients' lives. Clinical trials provide a chance to introduce innovative treatments to individuals who often have limited options. My dedication is fuelled by both a deep curiosity to explore new medical frontiers & genuine compassion for my patients. There's no greater reward than witnessing a treatment I've tested enhance or extend someone's quality of life. The hope and potential that clinical trials offer continually inspire & motivate me every day.

Tell us about an unforgettable moment you had as an investigator.

One of the most unforgettable moments in my career was when a patient, who had exhausted all standard treatment options, responded positively to a new therapy we were testing in a clinical trial. Seeing their health improves & knowing that our research played a part in extending their life was incredibly moving. Moments like these are what makes all the hard work worthwhile.

What's your personal vision as an investigator?

My vision is to help shape a future where treatments are increasingly personalised, targeted, and effective with fewer side effects. I view CRM as a vital partner in this mission, playing a key role in advancing clinical research in Malaysia & positioning us at the cutting edge of medical innovations. Furthermore, I am committed to inspiring & mentoring emerging researchers, providing them with the support & guidance necessary to pursue impactful, patient-centred research.

In your perspective, what's the biggest challenge in the field of Oncology?

The greatest challenge in oncology research is the inherent heterogeneity of cancer. Each patient's cancer exhibits unique characteristics, making it challenging to develop universal treatments. I am keen to see further advancements in personalised medicine, where treatments are specifically tailored to an individual's genetic profile. To accelerate this progress & enhance accessibility, increased collaboration between researchers, clinicians & technology experts is essential.

What's your advice for those who want to start their career in clinical research?

My advice is straight forward; Be curious & focus on the patients. Clinical research can be slow & challenging but its impact on patient care is deeply significant. CRM provides an excellent platform for young investigators to engage in clinical trials, offering vital resources & guidance. Always prioritize the well-being of participants & remember the core purpose of our work which is to improve lives. Seek out mentors, stay informed about the latest developments in the field, and remain open to learning from every experience, whether it's a success or a setback.



Dr Suhana and CRM study coordinators

Seated (L-R) : Abdul Hadi Hisham, Norjurina Abdul Talib, Dr Suhana Yusak, Erda Syerena binti Rosli, Yong Xian Lerk (Levy).

Standing (L-R) : Hidayati binti Mohd Sha'ari, Shamiza binti Ahmad Shaharudin, Siti Amirah binti Ishak, Anis Hazirah binti Asmali Jauhari, Nurul Afifah binti Rozkhaiddi



Dr Suhana at her office



Dr Suhana and CRM study coordinators

RISING STARS IN ENDOCRINOLOGY

Endocrinology has grown into one of Malaysia's most dynamic areas of clinical research, with over 100 studies conducted since 2012. This progress highlights the unwavering dedication of investigators and healthcare professionals driving innovation and advancing patient care. In this section, we spotlight rising stars in endocrinology, whose passion and contributions continue to elevate Malaysia's standing in clinical research.

Dr Tee Hwee Ching

Head of the Endocrinology Unit

Queen Elizabeth II Hospital



Areas of Interest in Research

Type 2 or Type 1 Diabetes, Obesity & Osteoporosis

I graduated from the University of Malaya in 2010 and obtained Membership of the Royal Colleges of Physicians from the Royal College of Physicians, UK, in 2015. In 2021, I completed my endocrinology fellowship training with the Ministry of Health Malaysia. I currently lead the Endocrinology Unit at Queen Elizabeth Hospital II, Kota Kinabalu, managing patients with endocrine disorders while actively contributing to research as a co-investigator and principal investigator for both Investigator-Initiated Research and Industry-Sponsored Research.

My research journey began in 2017 with case reports and retrospective studies, and it deepened in 2020 during my subspecialty training, where I conducted my first Investigator-Initiated Research. I have presented posters at scientific conferences and published papers in academic journals.

As I embark on my clinical trials journey, I am passionate about advancing research in underexplored endocrine conditions, particularly rare and genetic endocrine disorders. I believe focused research in these areas can significantly improve patient outcomes and contribute to the growing body of knowledge in endocrinology.

Dr Lee Siow Ping

Endocrinologist & Physician

Malacca Hospital



Areas of Interest in Research

Diabetes, Obesity & Thyroid

My journey into medicine began with earning my Medical Degree (MD) from Universiti Kebangsaan Malaysia (UKM) in 2008. I later achieved Membership of the Royal Colleges of Physicians (MRCP) in 2016 and completed a Fellowship in Endocrinology under the Ministry of Health, Malaysia in 2022. These milestones shaped my passion for advancing endocrinology and improving patient care.

Since starting my research journey in 2013, I've contributed to 3 industry-sponsored and 5 investigator-initiated studies, presented at 13 conferences and authored 2 publications. A career highlight was receiving the Young Investigator Award in 2022 from the Malaysian Endocrine and Metabolic Society.

My work focuses on diabetes, obesity, and thyroid disorders while advocating for more research into conditions like pituitary and bone disorders. I've also shared insights at professional seminars, addressing topics like diabetes management and lipid disorders.

I find fulfillment in contributing to clinical research and collaborations, which hold the potential to revolutionise patient outcomes in endocrinology.

Dr Gunavathy Muthusamy

Head of the Medical Department
& Consultant Endocrinologist and
Internal Medicine

Shah Alam Hospital



Areas of Interest in Research

Internal Medicine

I graduated from medical school in 1996 and earned Master's in Internal Medicine in 2000, completing my subspecialty training in Endocrinology in 2011. My research journey began with a Good Clinical Practice (GCP) course in 2004, which solidified my commitment to clinical research.

My first study, conducted in 2005 for my master's thesis, investigated coronary artery disease patients not meeting lipid targets, leading to improvements in patient management. During my Endocrinology training, I initiated an Investigator-Initiated Research (IIR) on Gastroenteropancreatic Neuroendocrine Tumours (GEP-NETs), the first study of its kind in Malaysia. This research addressed gaps in diagnosis and management, contributing to the formation of a GEP-NET clinical team in the country.

Other key projects include the Maverik Study (Malaysian Acute Vascular Event) in 2019, exploring genetic determinants of myocardial infarction and a recent IIR on lifestyle modification for metabolic syndrome. In 2023, I led an Industry-Sponsored Research (ISR) which is involved in evaluating the efficacy and safety of a novel agent in patients with viral lung infection.

Although my expertise is in Endocrine and Metabolic diseases, my broader interest in Internal Medicine guides my work as Head of Internal Medicine. I urge colleagues to engage in research to advance care, always prioritising patient safety.

Dr Eunice Lau Yi Chwen

Endocrinologist

Sibu Hospital



Areas of Interest in Research

Endocrinology particularly in the field of adrenal, parathyroid & neuroendocrine tumours.

Endocrinology has always been my passion & I've been fortunate to gain diverse research experience locally and internationally. The field is evolving rapidly & high-quality data is crucial to guide clinicians in making good decisions. Research benefits patients by providing access to treatments that might otherwise be unavailable or unaffordable, along with sponsor support. It also helps junior doctors build their careers and develop an interest in endocrinology.

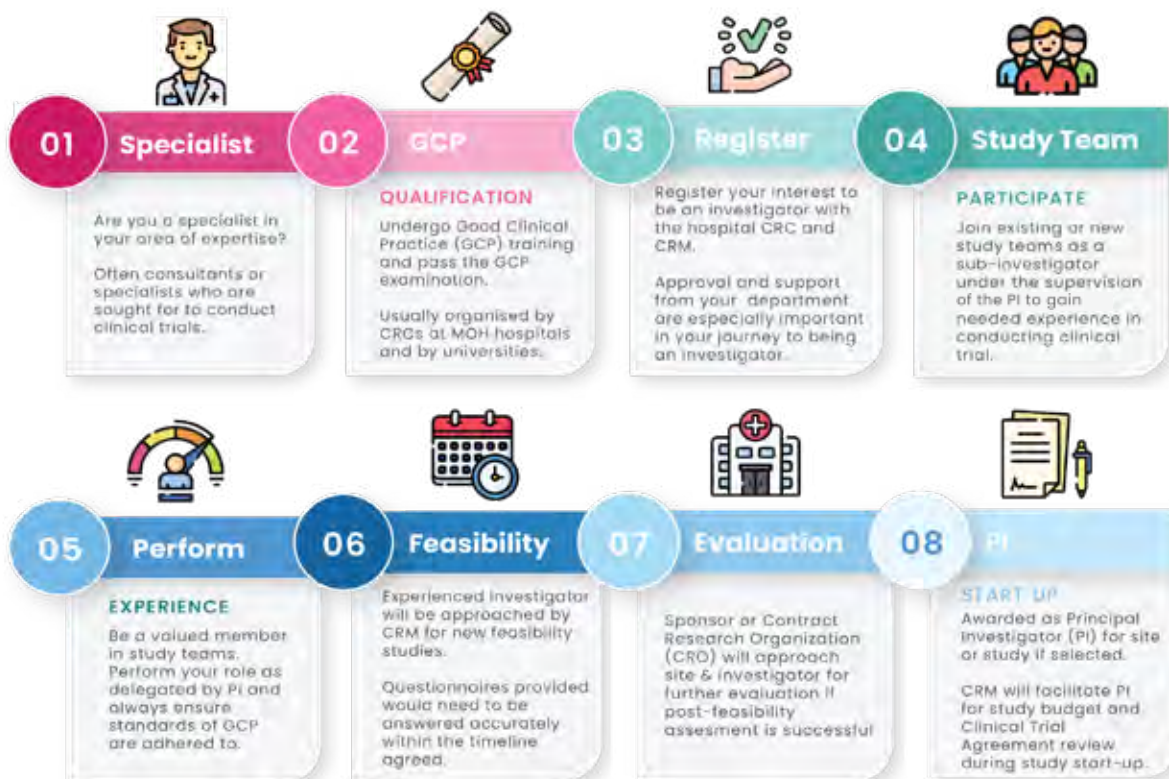
As a Sarawakian by birth, I graduated from the University of Otago in 2008 and have served in various districts in Sarawak, including Kuching, Sibu & Limbang. My endocrinology subspecialty training included time at Queen Elizabeth II Hospital, Putrajaya Hospital, University Malaya Medical Centre & Addenbrookes Hospital in Cambridge. In 2022, I returned to Sibu Hospital to establish its endocrinology services.

My research journey began in 2017, with my first Investigator-Initiated Research (IIR) approved in 2019, focusing on Subclinical Cushing's Syndrome in Metabolic Syndrome Patients. Currently, I'm involved in studies on cardiovascular safety and primary aldosteronism. My proudest achievement was developing my first research protocol in 2018, overcoming challenges to secure approval and funding. Additionally, my most notable publication appeared in the Journal of Clinical Endocrinology & Metabolism (JCEM) in 2022.

Research benefits patients by providing access to treatments that might otherwise be unavailable or unaffordable, along with sponsor support. It also helps junior doctors build their careers and develop interest in endocrinology

Dr Eunice Lau

ROADMAP TO BECOMING AN INVESTIGATOR



REGISTER AS AN INVESTIGATOR

<https://clinicalresearch.my/investigator-registration-form/>



Clinical Research Malaysia (CRM) facilitates as a one-stop centre for sponsored research. Below are some of the services CRM provides:



Feasibility studies & investigator matching



Consultation and management of clinical trial budget



Review of Clinical Trial Agreement (CTA) & Non-Disclosure Agreement (NDA)



Development & placement of study coordinators

GLOSSARY

Sponsored Research:

Research that is fully funded by a company/organisation. Protocol is developed by the sponsor and investigators are 'hired' to conduct the research. Common examples are drug clinical trials by pharmaceutical companies

Feasibility:

A process in evaluating the possibility of conducting the study at a region/site

Contract Research Organisation (CRO):

Research organisation that is outsourced by sponsor to provide research support

Study Coordinators:

Trained and qualified research personnel who support investigator in carrying out delegated study-related tasks

Accelerating Asia in Global Clinical Trials

CRM TRIAL CONNECT

8-9 May 2025
Kuala Lumpur, Malaysia

Event Highlights:

Clinical
Trials Day
2025



Collaborating Events:



Program Collaborators:



**Registration is Now Open, and
Sponsorship Opportunities are Available!**

Register Here



For more information, contact us at
event@clinicalresearch.my

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 System, ISO 45001:2018: Occupational Health and Safety Management System



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FEATURED SITE

Sultan Idris Shah Hospital, Serdang



Sultan Idris Shah Serdang Hospital (HSIS) serves as a vital healthcare hub for approximately 570,000 residents across Serdang, Putrajaya, Kajang and Bangi. Strategically located near the SKVE and Universiti Putra Malaysia's Faculty of Medicine, this 620-bed government hospital is a referral centre offering advanced secondary and tertiary care.

What makes this hospital stand out is its innovative approach to healthcare and sustainability. It operates with the 'Total Hospital Information System' (THIS), designed to streamline administrative and clinical processes for better patient care. The hospital is also Malaysia's first to use an aluminium-coated design, giving it a modern and distinctive look and it's surrounded by 45 acres of lush greenery. To keep things efficient and eco-friendly, it features a Thermal Energy Ice Cooling System that reduces electricity costs by producing ice during off-peak hours to cool the hospital during the day.

The hospital's sustainable design includes a unique aluminium-coated exterior and a Thermal Energy Ice Cooling System, which reduces electricity costs while maintaining a comfortable environment. Set amidst 45 acres of greenery, Sultan Idris Shah Hospital combines modern healthcare with a commitment to efficiency and environmental sustainability.

MAIN DEPARTMENTS

Department of Surgery

- General Surgery
- Anesthesiology and Intensive Care Unit
- Orthopedics
- Ophthalmology
- Emergency and Trauma
- Oral and Maxillofacial surgery
- Cardiothoracic
- Urology
- Otorhinolaryngology
- Wound care

Department of Medicine

- General Medicine
- Nephrology
- Rehabilitation Medicine
- Cardiology
- Psychiatry
- Pulmonology

Women and Child

- Obstetrics and gynecology
- Pediatrics
- Pediatrics Dentistry

FACILITIES

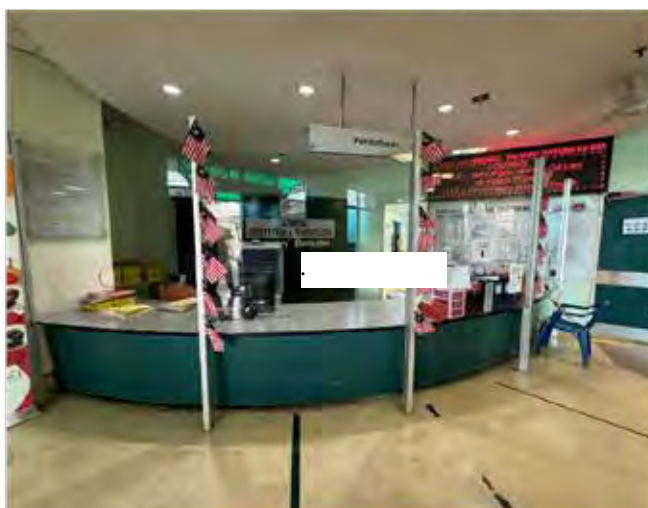
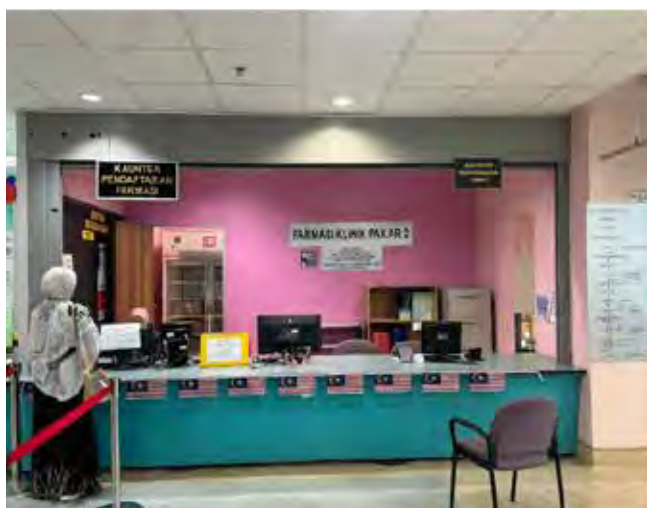
- Operation theatres
- Coronary care unit
- Cardiology care unit
- Intensive cardiothoracic care unit
- Paediatric intensive cardiothoracic care unit
- Invasive cardiac lab
- Non-invasive cardiac lab
- Cardiac recovery unit
- Medicine transfer unit
- Cardiac radiology department
- Cardiac emergency department

HSIS TEAM



HOSPITAL SPECIALTIES BASED ON THERAPEUTIC AREAS

- | | | |
|------------------|---------------|--------------------|
| • Cardiovascular | • Orthopedics | • Nephrology |
| • Dermatology | • ENT | • Gastroenterology |
| • Respiratory | • O&G | |
| • Pediatric | • Endocrine | |



TRIAL SITE BACKGROUND

The Clinical Research Centre (CRC) at Sultan Idris Shah Serdang Hospital was established in 2010 and has grown from a modest start with just 2 staff members to becoming a key hub for clinical research. Led by Prof Dr Goh Bak Leong, a Senior Consultant Nephrologist, the CRC is dedicated to advancing human subject research to transform clinical findings into new therapies, cures and guidelines that improve patient care.

As the hospital's research arm, the CRC supports physician-scientists in conducting clinical trials and contributes to building a vibrant research community. It provides essential services such as grant management, protocol development, feasibility studies, and statistical consultations, while also offering training programs like Good Clinical Practice (GCP) and Protocol Development to nurture future researchers.

The CRC remains committed to its mission of enhancing lives through research, fostering innovation, and strengthening the foundation of clinical science for better healthcare outcomes.



Standing (L-R) : Nor Faizah Binti Abdul Mutalib, Norjurina Abdul Talib (Associate Regional Manager), Nur Aliqah Dinti Nor Azman, Nor Ailiyana Saad, Yogabaanu A/P Ulaganathan and Siti Rohaya Binti Daud



Sultan Idris Shah Hospital, Clinical Research Centre entrance



CRC Fridge-Freezer Amenities



SC team are preparing samples

SNAPSHOT OF SPONSORED CLINICAL RESEARCH ACTIVITIES IN HSIS (2011-CURRENT)

Awarded	109
On-going	29
Recruiting	14
Start-up	25
Closed/Completed	15
Early termination	5

ISR BY THERAPEUTIC AREAS



ACCOMPLISHMENTS IN CLINICAL RESEARCH

Year	Accomplishment
2019	Highest enrollment in Malaysia & exceeding site target-Illumina RGH-01
2021	3rd Top Recruiter Globally- ONYX ONE Study
2024	Highest Recruitment In Malaysia - Lithos Study
	1st subject randomized in APAC- Kezar life Sciences
	1st subject randomized in Malaysia -Action3- Dimerix

MEET OUR TEAM

Ngu Lin Hui

Senior Study Coordinator, Sarawak General Hospital

*Individual CEO Award 2020 Recipient &
Team CEO Award 2021 & 2022 Recipient.*



About My Role

As the Senior Study Coordinator at Sarawak General Hospital, my role goes far beyond simply managing clinical trials. I serve as the central link between study sponsors, investigators, clinical sites, and stakeholders, ensuring trials progress smoothly by adhering to regulatory standards, meeting timelines and maintaining budgetary goals—all while safeguarding the integrity of collected data.

Additionally, I take pride in mentoring junior staff, guiding them to manage clinical trials with efficiency and precision. It's fulfilling to contribute to not just the success of each study but also to the growth of a skilled and dedicated research team.

What inspired you to be part of the clinical research industry and what drives you to move forward?

My decision to join the clinical research industry comes from a deep-rooted passion for science, medicine, and a desire to contribute to something that creates a meaningful impact on people's lives. The idea of working on projects with the potential to bring new therapies to market and offer patients hope, especially in areas of unmet medical need, is incredibly inspiring. Knowing that the research I help facilitate could lead to treatments for patients suffering from chronic illnesses drives my commitment. Whether it's advancing cancer treatments, addressing rare genetic diseases, or improving vaccines, being part of something that alleviates suffering and helps patients is deeply fulfilling.

Clinical research can be a lengthy and intricate journey, but those moments when a trial results in a breakthrough or a new drug approval are truly inspiring. These achievements bring a profound sense of fulfilment and strengthen my determination to pursue the next milestone.

What has been your greatest learning opportunity in clinical research?

For me, the most significant learning experience arose from my participation in large-scale, multi-phase clinical trials of various therapeutics. This involvement deepened my understanding of trial management, global collaboration, regulatory processes, and the vital importance of patient safety and data integrity. It equipped me with a well-rounded skill set, allowing me to manage future clinical trials with enhanced confidence, foresight, and a strong focus on patient-centered care.

Important value/criteria that has helped you support your role.

As a Senior Study Coordinator, my effectiveness comes from core values like ethical integrity, attention to detail, effective communication, adaptability, strong organisation, and a commitment to continuous learning. These principles guide me in navigating the complexities of clinical research, ensuring trials are conducted safely, ethically, and efficiently. Upholding these values allows me to contribute to advancing scientific knowledge and developing therapies that can improve patient outcomes worldwide.

In your daily work-life, what keeps you motivated in your workplace?

Teamwork is at the heart of my daily motivation. The shared goals, collaborative spirit and support from colleagues create a fulfilling and dynamic work environment. Diverse perspectives and collective problem-solving enhance both the efficiency of clinical trials and my drive to give my best. This sense of unity inspires me to pursue excellence and deepens my commitment to the vital work we do in clinical research.

Saidatul Nisaa Shamshul Kamal
*Associate Manager of Quality,
 and Integrity & Governance Unit (IGU)*

Team CEO Award 2021 Recipient



Roles and Responsibilities

I joined CRM in 2020 as Associate Manager for Quality and in 2021, my role expanded to include integrity and governance with the establishment of the Integrity and Governance Unit (IGU). I ensure CRM's compliance with ISO 9001:2015 and ISO 37001:2016 standards, coordinate annual third-party audits, and lead the Internal Audit team to maintain regulatory and procedural compliance.

I also manage customer feedback through the CRM Customer Satisfaction Survey, gathering input from Investigators, Sponsors and CROs. Additionally, I oversee the QMS documentation system, review document revisions and provide process enhancement recommendations. Regularly, I report to the Board and Senior Leadership Team on ISO compliance and any issues related to the Quality and Anti-Bribery Management Systems.

How does the Integrity and Governance Unit ensure the quality and smooth execution of clinical trials?

Quality and integrity are essential for reliable clinical trials, ensuring consistent, trustworthy conduct. The Integrity and Governance Unit (IGU) plays a key role by developing and enforcing SOPs, maintaining consistency and quality across trial processes. These procedures clarify staff roles and responsibilities, fostering accountability. The IGU also ensures compliance with local and international regulations, including Good Clinical Practice (GCP) guidelines, through regular audits and assessments. By upholding these standards, the IGU strengthens trial integrity and builds trust with stakeholders and participants.

What challenges do you face in upholding ethical standards, and how do you address them?

In high-pressure environments, it's crucial to prioritize ethics over short-term gains. As the manager of quality, integrity, and governance at CRM, I must set a strong example. With my role comes the pressure to minimize mistakes and offer sound recommendations. Navigating conflicts of interest or favouritism can challenge my neutrality, so I focus on clear communication and transparency to support ethical decision-making. I also strive to keep an open mind, ensuring that rational judgment prevails over emotions.

What part of your role do you find most rewarding?

The role is highly rewarding due to the tangible impact of quality improvements on the organization, such as enhanced processes, reduced deviations, and increased customer satisfaction. It's fulfilling to contribute to the company's success, foster a culture of continuous improvement, and see the team grow in their understanding of quality and anti-bribery principles. Being part of a team focused on excellence and positive change adds to the role's satisfaction.

Do you liaise closely with any specific departments or external entities?

As part of the core functions of the Integrity Governance Unit (IGU), specifically in Integrity Governance and Integrity. I work closely with the CRM Code of Conduct Committee to raise awareness about our Code of Conduct and anti-corruption practices. This includes sharing updates and supporting actions on COC violations. I also act as the primary contact for agencies like SIRIM, BPIA (MACC), and the Ministry of Health Integrity Unit, ensuring strong relationships and compliance with integrity standards.

What drives you in your day-to-day work?

What drives me to work is a 220ft 4-coach train carriage along with 200k other passengers every morning.

Haha! But on a more serious note, what drives me in day-to-day work is a combination of impactful results and the collaborative spirit of the team. Knowing that my efforts contribute to meaningful improvements and positive outcomes keeps me motivated. I find it rewarding to see how our work enhances processes and benefits the company. The camaraderie and support of a dedicated team make a big difference. Sharing ideas, problem-solving together, and celebrating our successes create a motivating environment. While a good cup of tea adds enjoyment to my day, I also enjoy light-hearted conversations with my colleagues. It's those small moments of connection that help keep the energy up (*and tension down*).

CRM IN PHOTOS



CRM with Dabur Research Foundation (Althea DRF Life Sciences) and Meluha Therapeutic.

9
Aug



CRM met with Clinical Research Committee of PhAMA.

14
Aug



CRM met with Luise, Clinical Research Director, Singapore & Malaysia of MSD.

14
Aug



CRM met with Advance Pact.

14
Aug



CRM met with Ms. Nadiah, President and Ms Allida, Vice President of Malaysian Rare Disorders Society (MRDS).

22
Aug



CRM met with Ms He Shuyun, Clinical Trial Oversight Manager, SEA at Amgen.

22
Aug



CRM with Geraldine Tong from The Sunday Star & Mr Syed Johari, a clinical trial participant.

22
Aug



CRM met with the CMIC team.

23
Aug



CRM re-connected with Triphasic team.

26
Aug



CRM with Mr Joseph Prasetya, CEO & Co-Founder of Obatica and Dr Amy Prawira, Founder of Obatica & Head of Oncology Clinical Trials at Prince of Wales Hospital in Australia.

26
Aug



CRM with HE Florentino Batista-González, Ambassador of Cuba along with Attaché Ms Saimi Reyes Carmona, with the presence of Minister of Health at MOH.

28
Aug



CRM with Dr Huren, CEO & Co-Founder of Oncoshot

30
Aug

CRM IN PHOTOS



CRM had an engagement with Columbia Asia Bukit Rimau.

3
Sep



CRM with several biopharmaceutical organisations from China

4
Sep



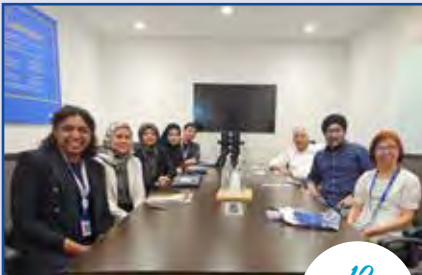
CRM with Mr Mohan Manthiry, Founder & CEO of InfoMed.

5
Sep



CRM had an engagement with Novugen team.

5
Sep



CRM had engaging meet with the Colorectal Cancer Survivorship Society Malaysia (CORUM).

12
Sep



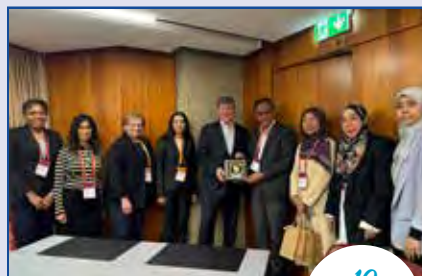
CRM with MSD & M.S. Ally Pharma Sdn Bhd.

17
Sep



CRM with the Novo Nordisk team.

18
Sep



CRM with the Minister of Health along with Dr Ros Suzanna (Head of Speciality in Oncology & Radiotherapy) and Princess Margaret Cancer Center team.

19
Sep



CRM with Dato' Indera Dr Nor Azimi, Deputy Director General of Health, providing an overview on CRM's role in developing the local clinical research ecosystem.

19
Sep



CRM congratulating Dr Yeoh Wei Sien on his appointment as Head of CIC.

19
Sep



CRM with Dr Craig Tipple, Medical Director & Ms Sasikala Siva, Clinical Quality Assurance Manager from DNDi.

26
Sep



CRM with IIUM Clinical Research Centre.

30
Sep

CRM IN PHOTOS



CRM with Kyushu University Hospital, National Center for Global Health and Medicine & CMIC.

7
Oct



CRM with Dr Kit Huckvale, Validitron Lead (Research Platform) of University of Melbourne.

10
Oct



CRM met with AstraZeneca team.

10
Oct



CRM met with Gilead Team.

25
Oct



CRM had engaging meet Bristol Myers Squibb (BMS) team.

30
Oct



CRM with the Tropical Infectious Diseases Research & Education Centre (TIDREC) and the University of Oxford team.

6
Nov



CRM met with GlaxoSmithKline (GSK) team.

7
Nov



CRM with Mr Kamran Khan, Business Development Director at Smooth Drug Development.

14
Nov



CRM had an engagement with Syneos Health team.

16
Nov



CRM with Dr Rethina, Founder of Realign Training & Consultancy.

16
Nov



CRM with Thomson Hospital Kota Damansara CRC Director, Dr Kasturi Nair & Revthy Karunanithee (Admin Executive).

16
Nov



CRM met with Mr Jawad, Medical Monitor & Head of Quality from International CRO, Acceler8 Clinical Research.

3
Dec

CRM IN PHOTOS



CRM with Dr Fina Tams, Public Health Specialist & Prof Teguh Haryo Sasongko from IMU.

6
Dec



CRM had an engagement with Novo Nordisk team.

17
Dec



CRM met with Ms Lovy Beh, Chairman of Lovy Pharmacy and Executive Director BP Healthcare Group.

19
Dec

Visit our FACT page to find a clinical trials near you

1



VISIT CRM FACT WEBSITE

2



SEARCH
Navigate through the conditions listed to find relevant clinical trial. You could also find the locations of the clinical trial you are looking at

3



REGISTER
Send your details to us by completing the registration

4



SEND TO SITES
We send your details to the enrolling site(s)

5



CALL FOR PRE-SCREENING
If you're eligible, you will be contacted by our Study Coordinator for pre-screening. If pre-screening is successful, you can be enrolled in the study

6



NOT ELIGIBLE?
Don't lose hope! We will contact you again when there's a new clinical trial at site



SCAN HERE

<https://clinicalresearch.my/condition/>

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