

CRM Bulletin

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**GUIDED BY VISION,
DRIVEN BY RESEARCH**

**RESEARCH
PERSONALITY:
DATUK DR NOR
FARIZA NGAH**

FEATURED SITE

Tengku Ampuan
Afzan Hospital

**RIISING STARS
IN CARDIOLOGY**





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 1st Bulletin issue of 2025!

As the year unfolds, it's hard to believe we've already crossed the first quarter. These early months have been filled with purpose, progress and fresh momentum. And it's only just the beginning.

This issue captures the highlights from January to April, marked by meaningful strides in public awareness, capability building and talent development. Our I AM AWARE campaign continued to engage the public in important conversations about clinical research, while a series of workshops and capacity-building sessions brought together investigators, site teams, and key stakeholders to support site readiness and strengthen Malaysia's clinical research infrastructure.

We also proudly welcomed the first batch of our 2025 Centre of Excellence (CoE) Trainees, who have officially begun their journey in shaping the future of Malaysia's clinical research workforce.

One of the standout stories in this issue is our Research Personality feature on Datuk Dr Nor Fariza Ngah, Deputy Director-General of Health (Research & Technical Support). Her inspiring journey reflects the power of research to drive meaningful change in healthcare, guided by passion, resilience and vision.

We're also excited to showcase Malaysia's Rising Stars in Cardiology — emerging leaders who are pushing boundaries in this vital field. In our newly introduced Site Spotlight, we highlight the extraordinary efforts of Hospital Sultanah Aminah in leading patient recruitment for an Ulcerative Colitis trial. Meanwhile, our Featured Site segment turns the spotlight on Hospital Tengku Ampuan Afzan, a centre committed to advancing clinical excellence and setting new standards in site performance.

Here's to new beginnings, impactful milestones and the stories that continue to inspire us as we move through 2025.

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



MiLeS Debut: Lessons from the SIRIM Audit Experience

9 January 2025 – The first session of MiLeS (Mini Learning Series) kicked off with a talk on “Experience from SIRIM Audit” by Puan Azirah Binti Osman, Senior Study Coordinator at Hospital Seri Manjung. She shared valuable insights and practical tips from her audit experience, helping participants better understand audit preparedness and improve site readiness.



PhAMA Intro Series: Nurturing the Next Generation of Clinical Research Talents

9 January 2025 – The PhAMA Intro Series on Clinical Research, organized by the Pharmaceutical Association of Malaysia and its Clinical Research Committee, gathered students and professionals from diverse backgrounds. Clinical Research Malaysia (CRM) shared an overview of Malaysia’s clinical trial landscape and emerging opportunities. Aiming to create 4,000 skilled jobs by 2033, CRM remains committed to nurturing talent and strengthening industry collaboration.



Global First: Sarawak General Hospital Screens First Patient in Endobronchial Ablation Study

14 January 2025 – Congratulations to Dr Kho Sze Shyang and study coordinator Noor Annisa Darman from Sarawak General Hospital for successfully screening the first patient globally for a medical device study on endobronchial ablation.

Their dedication and teamwork mark a major milestone in advancing clinical research and improving patient care. The team now looks forward to the upcoming first global ablation case.



A Day with Prof Tony Mok: Inspiring the Next Generation of Oncology Researchers

17 January 2025 – CRM & University Malaya Medical Centre (UMMC) had the honour of hosting Prof Tony Mok, a globally renowned figure in lung cancer research. During the session, Prof Mok shared his personal journey & insights on becoming an International Principal Investigator, offering inspiration to aspiring oncology researchers. The programme also provided a meaningful platform for local investigators to connect, exchange experiences, and explore future collaborations.



Global 1st Recruiter: Malaysia Leads in First-in-Human Study

23 January 2025 – Dr Voon Pei Jye, Medical Oncologist at Sarawak General Hospital & his study team have successfully enrolled the 1st participant in an Advanced Solid Tumor First-in-Human (FIH) study, placing Malaysia ahead of other global sites. This marks the first FIH trial by BeiGene, following its partnership with Clinical Research Malaysia in December 2024. This milestone reflects the dedication of the entire team, especially study coordinators Fong Yan Ching, Cindy, Haziqah, Lin Hui, and Li Fang, and showcases Malaysia's growing capabilities in early phase research.



Introducing CRM to Primary Care Practitioners

24 January 2025 – CRM Feasibility Specialist, Nur Ain Amir delivered a session on 'Introduction to CRM' during the Club Journal FMS Wilayah Persekutuan that was held at Klinik Kesihatan Kuala Lumpur. The session aimed to raise awareness among healthcare professionals on the role of Clinical Research Malaysia and the opportunities to advance clinical research within the primary care setting.



Future Pharmacists Explore Clinical Research with CRM

13-23 January 2025 - 3 Provisionally Registered Pharmacists (PRP) and 1 Master's in Pharmacy Practice student from IMU recently completed their Clinical Research module attachment with CRM. The trainees were introduced to Malaysia's clinical research landscape, including Good Clinical Practice, regulatory frameworks, and the pivotal role of study coordinators at trial sites.

The programme offered both knowledge sharing & hands-on experience, preparing trainees for future roles in the clinical research industry.



Sharing Malaysia's Experience at Pakistan's First Clinical Trials Summit

17-18 February 2025 - CRM took part in the first Clinical Trials Summit of Pakistan 2025, organised by Aga Khan University to chart the future of clinical research in the country. It was an honour for CRM to share Malaysia's experience and journey in advancing clinical trials. Wishing continued success to the organisers and stakeholders as they drive this important mission forward.



1st Nurturing New Talents in Sponsored Research (NNT) of 2025

24 February 2025 - CRM successfully organised a seminar on NNT in sponsored research at Hospital Raja Permaisuri Bainun Ipoh, bringing together aspiring investigators to enhance their research capabilities. Featuring valuable insights from Dr Chan Ming Jun and Ms Lydia Paul, the session provided guidance on advancing in clinical research.



Novartis Explores Research Collaboration in Malaysia

25 February 2025 - The Novartis Global Health & Biomedical Research team were in Malaysia for study site visits and had the opportunity to engage with National Institute of Health team along with CRM & Clinical Trial Unit of Hospital Ampang, with the meet chaired by Datuk Dr Nor Fariza bt Ngah, Deputy Director General of Health (Research & Technical Support).

Much of the discussion were focused on Novartis Global Health's research priority areas, including malaria. CRM, CTU & NIH team highlighted on Malaysia clinical research capabilities during this discussion, topics of which were further focused on during Novartis's team visit to Sarawak General Hospital CRC later that week.



CRM at University of Nottingham Malaysia Careers & Internship Fair 2025 (UNMCIF2025)

26 February 2025 - CRM participated in the University of Nottingham Malaysia Careers and Internship Fair 2025. Representatives Amin, Syifa & Puteri had the opportunity to connect with students from science-related fields such as Biomedical Science, Biotechnology, Pharmacy and Biosciences.

The event served as a valuable platform to raise awareness about the clinical research industry and CRM's Centre of Excellence program. The team engaged in insightful discussions with students about their career aspirations and were inspired by their enthusiasm. CRM looks forward to continuing to inspire future talents in clinical research.



Patient Recruitment & Retention Workshop 1/25

26 February 2025 - CRM held its 1st Patient Recruitment & Retention workshop in February, led by 'Izzah 'Atira Hisham, CRM Associate Regional Manager & Safiah Sabrina Hassan, CRM Clinical Research Patient Recruitment Specialist. The workshop brought together 21 participants from internal teams and external stakeholders, focusing on strategies to improve patient recruitment and retention in clinical trials. The session was interactive, encouraging valuable discussions and knowledge-sharing.



Rare Disease Day Celebration & I AM AWARE Roadshow

27 - 28 February 2025 - In conjunction with Rare Disease Day, Tunku Azizah Hospital organised an awareness event under the theme “More Than You Can Imagine.” CRM took the opportunity to kick off its first ‘I Am Aware’ Roadshow of 2025 at the hospital, collaborating with the CRC team to promote awareness on clinical trials in rare diseases.

The event also brought together advocacy groups such as the Malaysian Rare Disorder Society and Prader-Willi Syndrome Association. During the session, CRM’s Ms Asha Thanabalan delivered a talk titled “Clinical Trials in Rare Disease: A Hope for the Future.”



First TA Guru Session Kicks Off with Oncology Focus

28 February 2025 - CRM successfully held its first TA Guru session, featuring Dr Rufus Jesudass from Hospital Kuala Lumpur, who shared valuable insights on solid tumours and oncology trials. His expertise brought depth to the session, enriching participants’ understanding of therapeutic area-specific research. CRM looks forward to continuing this knowledge-sharing series in the upcoming sessions.



Dialogue with National Pharmaceutical Regulatory Agency (NPRA)

5 March 2025 - CRM hosted the NPRA-Industry Stakeholder Engagement at its Centre of Excellence, with over 24 industry organisations represented. The discussion with NPRA was highly welcomed by all attendees. Dr Azuana Ramli, Director of NPRA, and Pn Rosliza Lajis, Deputy Director, were present, along with the Investigational Product & Safety team led by Dr Zaryl Harza Zakaria, who shared valuable insights on NPRA’s latest developments in clinical trial regulations.

Early engagements like these are crucial, ensuring that all voices are heard and contributing to greater support when implementation begins. CRM extends its gratitude to the NPRA team for leading this effort and looks forward to more productive dialogues in the future.



CRM Centre of Excellence 2025 Kicks Off

6 March 2025 - The 1st batch of the CRM Centre of Excellence 2025 is officially underway! This program is designed to provide participants with the knowledge, skills, and hands-on experience required to excel in the field of clinical trials. As they begin this journey, it is hoped that the program will serve as a springboard for their careers, empowering them to make meaningful contributions to the future of clinical research. CRM wishes all participants the very best in their pursuit of excellence.



CRM Visits Cytopeutics

11 March 2025 – CRM had the privilege of visiting Cytopeutics' office in Cyberjaya & was truly impressed by the impactful work being done by their team in clinical research. From their R&D focus in osteoarthritis, ischaemic heart disease and stroke, to their landmark research in Graft Versus Host Disease, Cytopeutics is making significant strides in advancing stem cell research in Malaysia. It was a meaningful visit that highlights the value of collaboration in shaping the future of healthcare.



Welcoming Sarawak Deputy Premier to CRM HQ

12 March 2025 – It was an honour to host a visit by Deputy Premier of Sarawak, YB Datuk Amar Prof. Dr. Sim Kui Hian in CRM HQ. As the founding father to the growth of clinical research ecosystem in Sarawak, YB Datuk Amar's insights in furthering the landscape was truly valuable, and CRM welcomed the opportunity to discuss on the new opportunities arising in this space.



Another Mini Learning Series (MiLeS) Completed!

20 March 2025 - CRM wrapped up another engaging MiLeS session focused on Building Stronger Collaboration with Investigators. Special thanks to Salina Lisang and Puteri Nur Najwa for sharing their valuable insights and experiences, reflecting true dedication to advancing clinical research.

The session highlighted the vital role study coordinators play as the right hand of investigators, and how strong collaboration is key to trial success. Thank you to all participants for your enthusiasm and commitment to continuous learning. Here's to taking more MiLeS together!



CRM Visits Oncode Scientific

24 March 2025 - Another amazing facility visit, with CRM visiting and engaging with the team at Oncode Scientific, a CAP accredited laboratory based in Shah Alam, that provides cutting-edge diagnostic solutions. Much of the discussion was focused on the need for data on incidences of cancer mutations in Malaysia, thus enabling opportunities in precision medicine trials.



CRM Holds First Company Meeting of the Year

24 March 2025 – CRM held its first company-wide meeting of the year, aligning the team towards achieving the KPIs and targets set for 2025 and Vision 2033. With a growing workforce of 272 employees, CRM reaffirmed its commitment to operational excellence and upholding its core values and code of conduct. The organisation continues to focus on delivering clinical trials with speed, quality, and reliability as a Global Trusted Research Management Organisation.



CRM Hosts MDA Delegation for Strategic Engagement

27 March 2025 – It's an engagement between 2 MOH organisations, with CRM hosting a meet with delegation from Medical Device Authority, led by its Chief Executive Officer, Dr Muralitharan Paramasua. Much of the discussion were focused on CRM's journey being a Global Trusted Research Management Organisation, rooting from its operational excellence and organisational sustainability.



Strengthening Clinical Supplies Management through Targeted Training

11 April 2025 - CRM HKL and the HKL Pharmacy Department partnered with the MSD team to conduct a focused training session for Study Coordinators & trial pharmacists on clinical supplies storage and temperature management. The session enhanced site team understanding of investigational product inventory control, temperature monitoring and dispensation practices, while reinforcing awareness of temperature excursion risk assessments. These elements are critical in maintaining drug integrity and ensuring patient safety.



CRM Hosts French Club Santé Delegation

15 April 2025 – CRM had the pleasure of hosting members of French Club Sante, a group of representatives from French-based healthcare companies, along with His Excellency Axel Cruau, French Ambassador to Malaysia. The meet provided an excellent platform for CRM to connect and introduce Malaysia's clinical research ecosystem, exploring new collaborative opportunities together.

REFRESHER WORKSHOP 1/2025



1st Good Clinical Practice Refresher Workshop of 2025 Held Virtually

15 April 2025 -- CRM successfully conducted its 1st GCP Refresher Workshop series of 2025 in a virtual format. It's designed to reinforce essential Good Clinical Practice principles. Thanks to the CRM speakers Ms Syifa Mazlan, Ms Puteri Nur Aliah and Ms Yoong Kai Shen for delivering engaging sessions filled with practical insights. The workshops provided the participants with a valuable opportunity to refresh their knowledge & stay aligned with regulatory expectations.



Nurturing New Talents in Sponsored Research Held at Hospital Pulau Pinang

17 April 2025 - CRM successfully held Nurturing New Talents in Sponsored Research at Hospital Pulau Pinang. The session aimed to inspire and guide aspiring investigators in their clinical research journey.

Special thanks to Dr Soo Hoo Hwoei Fen, Consultant Clinical Oncologist at Hospital Pulau Pinang, and Mr Chan Wei Quan, Manager of Clinical Operations at Johnson & Johnson, for sharing their invaluable insights. The seminar provided participants with the motivation and knowledge to explore sponsored research opportunities



1st Virtual Protocol Compliance Workshop in 2025

17 April 2025 – CRM held its first Virtual Protocol Compliance Workshop of the year, highlighting the importance of following clinical trial protocols. Dr Lee Keng Yee from MREC and Mr Syed Amir shared helpful insights and guidance from a regulatory perspective. Participants gained useful knowledge to support better compliance with international standards.



Productive Visit to HSNZ for Coffee Talk Session

24 April 2025 – CRM CEO Dr Akhmal Yusof and team spent a fulfilling day at Sultanah Nur Zahirah Hospital (HSNZ) for a Coffee Talk session. The visit included a tour of the newly established CRC CRM office, an inspiring space that supports future clinical research excellence. The session brought together the Hospital Director, Deputy Director, and over 30 investigators, both seasoned and new, for meaningful discussions on the clinical trial landscape. With HSNZ's strong recruitment performance and growing momentum, the site is well positioned for continued success in advancing research.

SPOTLIGHT FEATURE

Bridging Borders: Strengthening UK-Malaysia Clinical Research Ties



UNITED KINGDOM, 14 - 17 April 2025 - April marked a meaningful milestone in Malaysia's global outreach as the Director-General of Health Malaysia, Datuk Dr Muhammad Radzi, together with Clinical Research Malaysia's CEO, Dr Akhmal Yusof, embarked on a strategic visit to the United Kingdom. The engagements focused on strengthening research ties, driving innovation and showcasing Malaysia's growing presence in global health.

The visit began at St George's University and Hospital in London, where discussions explored potential collaborations in medicine, diagnostics and healthcare technology. These aligned with IADATA's focus, particularly in advancing dengue diagnostic solutions. A session hosted by the Academy of Medical Sciences UK further recognised Malaysia's efforts in eliminating Hepatitis C and opened new opportunities for future partnerships.

Following this, Datuk Dr Radzi and Dr Akhmal met with Professors Martin Hibberd and Chris Drakeley at the London School of Hygiene and Tropical Medicine to explore collaborative research opportunities in infectious diseases and global health.

In a separate session, the Malaysian healthcare diaspora gathered at Malaysia Hall London for an engaging dialogue with Datuk Dr Radzi. The discussion covered professional development, return prospects and roles in clinical research. The presentation of the EASE study also sparked meaningful questions and interest from attendees.

The visit to Wellcome offered opportunities to align efforts in tackling antimicrobial resistance and infectious diseases. CRM was warmly welcomed by Dr Alexander Pym, who expressed interest in exploring collaboration.

The trip concluded with a productive meeting at Oxford University with Professor Trudie Lang and her team, where the EASE data and Global South strategy were positively received. Professor Sir Peter Horby also shared enthusiasm for potential collaboration, particularly in monoclonal antibody research at the Phase 1 Unit in Sarawak.

These meaningful engagements reflect Malaysia's readiness to build impactful global research partnerships and contribute to the future of healthcare.

Malaysia Featured on Global Stage at American Association for Cancer Research (AACR) Annual Meeting 2025



CHICAGO, 25 - 30 May 2025 – Malaysia was proudly represented at the American Association for Cancer Research (AACR) Annual Meeting 2025 that was held from 25-30 April 2025. It is one of the world's largest gatherings for cancer research, AACR25 brought together over 21,000 participants from more than 80 countries, reaffirming its status as a global stage for cutting-edge scientific exchange.

Beyond the conference halls, CRM actively engaged with various biotechs and sponsors to attract early phase and First-in-Human trials to Malaysia. Strategic discussions with Kivu Biosciences, Revolution Medicines and Novartis focused on oncology research, regulatory pathways and building a strong ecosystem to support advanced trials, including radioligand therapy (RLT). Meetings with other industry leaders also opened promising pathways for collaboration in translational research and drug development.

CRM further reconnected with Malaysian researchers from institutions such as Cleveland Clinic and the Chinese University of Hong Kong. In a separate engagement, CRM visited the MIDA Chicago office to share updates on Malaysia's clinical research landscape and explore investment opportunities with support from MIDA's healthcare and research sector efforts.

At the heart of Malaysia's participation was Professor Cheong Sok Ching (Chief Scientific Officer, Cancer Research Malaysia), who shared her groundbreaking work on the MeMoSA oral cancer project during the Presidential Select Symposium. Her presentation, in collaboration with the Ministry of Health, was a pivotal moment that spotlighted Malaysia's role in shaping the future of oral cancer research.

In addition, CRM is thrilled to witness our collaborator in PMCC, Professor Lilian Siu (Director of the Phase I Clinical Trials Program, Princess Margaret Cancer Centre, Canada) being elected as AACR President-Elect. PMCC has been a value partner in CRM Phase 1 Mission of Excellence.

As the meeting concluded, Malaysia's innovative projects like Project MeMoSA and Project ROSE were highlighted in the final plenary session with Dr Fong Chin Heng and Associate Professor Pang Yong Kek recognised for their work on cancer treatment and prevention.

Malaysia Charts Path to Regional Leadership in Clinical Trials



PUTRAJAYA, 21 April 2025 - Malaysia continues to strengthen its position as a leading destination for sponsored clinical research, reaching new milestones as highlighted in Clinical Research Malaysia's Annual Report 2024. The launch was officiated by YB Datuk Seri Dr Dzulkefly Ahmad, Minister of Health Malaysia and marked a significant step forward for the country's research ecosystem.

The report recorded 267 new sponsored clinical trials initiated in 2024 with a total contract value of over RM 340 million. This marks the highest investment ever documented since CRM's establishment in 2012. Malaysia also gained momentum in early phase research, awarding the highest number of First-in-Human studies since the launch of the Phase 1 Realisation Project. These studies are conducted at Sarawak General Hospital, the country's First in Human accredited centre.

"These accomplishments reflect Malaysia's growing capabilities and proven track record in delivering global clinical trials with speed, quality and reliability," said the Minister of Health in his keynote address. "From our dedicated investigators and study coordinators to industry partners who share our commitment to expanding access to innovative research treatments, 2024 stands as a testament to what we can achieve through purposeful collaboration. I hope this momentum continues to inspire further excellence in research that benefits our patients, strengthens our healthcare system, and raises Malaysia's profile on the global stage."

The launch event also featured the signing of a Memorandum of Understanding between Clinical Research Malaysia and CSI Medical Research, a ClinChoice Company. This partnership aims to promote Malaysia's clinical trial capabilities to international biotechnology organisations and to support workforce development through joint initiatives.

Aligned with its Vision 2033, CRM continues to invest in professional development and regional collaboration. Its Centre of Excellence has produced 30 graduate trainees equipped with a foundation in clinical research. Together with the Ministry of Health, CRM is also leading an ASEAN-level initiative to boost industry sponsored clinical trials across the region. With continued progress and collaboration, Malaysia is steadily advancing towards its goal of becoming a preferred hub for clinical research in the region.

RESEARCH PERSONALITY

Datuk Dr Nor Fariza Ngah

*Deputy Director General (Research & Technical Support),
Ministry of Health*



Bridging Research and Healthcare: Datuk Dr Nor Fariza Ngah's Journey in Advancing Clinical Research in Malaysia

Research is not just about publishing papers, it's about identifying unmet needs, improving patient care and shaping the future of medicine.

For Datuk Dr Nor Fariza Ngah, clinical research is more than just an academic pursuit, it is a driving force behind meaningful change in healthcare. As the Deputy Director-General of Health (Research & Technical Support), she has played a pivotal role in strengthening Malaysia's clinical research landscape, bridging fundamental research with clinical applications and mentoring the next generation of researchers. Her journey from a young medical officer co-authoring her first research paper to becoming a leader in Malaysia's healthcare system is a testament to the power of persistence, innovation and a vision for the future.

How did your journey in research begin?

My first introduction to research came when I was a medical officer in a neurology posting. My specialist encouraged me to co-author a case study on myasthenia gravis management, which became my first published work.

However, my real research journey began during my master's program, where I struggled to find the right research topic. I faced multiple rejections before finally joining a parasitology research team, where I worked on a study on vitamin A deficiency among the Orang Asli.

At the time, research wasn't seen as a priority for service doctors, but during my subspecialty training, I realized its importance. **Research is what helps us identify gaps in healthcare and improve treatment options.**

What led you to focus on ophthalmology research?

When I returned from my subspecialty training in 2003-2004, ophthalmology research in Malaysia was still in its infancy. Age-Related Macular Degeneration (AMD) research was gaining global attention and I saw an opportunity to contribute and elevate Malaysia's role in this field.

I conducted my first observational study on photodynamic therapy (PDT) treatment, an approach that was still unconventional. Novartis recognized my work and supported my participation in international research conferences.

This recognition led to Malaysia's first global landmark study in retina research, and soon, our research unit became known.

When a new study emerged, they started looking for us. That was when I knew we had made an impact.

What is your role in shaping Malaysia's clinical research ecosystem?

As Deputy Director-General of Health (Research & Technical Support), my role extends beyond ophthalmology. My focus is on bridging fundamental research with clinical applications to ensure that discoveries made in the lab translate into real-world treatments for patients.

Previously, fundamental research often remained within laboratory settings. Now, we ensure clinician involvement from the early stages so that research findings can be applied in clinical settings.

I have also pushed for standardizing data collection, integrating Artificial Intelligence (AI) into clinical research, and enhancing collaborations between academia, industry, and public healthcare.

What initiatives have you introduced to support young researchers/investigators?

Mentorship is something I strongly believe in. Many young researchers have great ideas but don't know where to start. That's why I introduced:

- Mini-grants (RM50,000) to encourage early-stage research.
- The Scientific Review Board (SRB) to help refine research proposals.
- The "Next Generation Retina" mentorship program, which pairs young doctors with experienced researchers.

To aspiring researchers, I always say: "Every clinical question is a potential research idea. If you see a way to improve treatment, that's where research begins."

What is the proudest research achievement in your career?

One of my proudest moments was our contribution to the Everest 2 study, a global trial on combination therapy for AMD. Malaysia was among the largest patient contributors and the study's success demonstrated that Asian treatment approaches such as PDT, could be just as effective as Western monotherapies.

Even today, Everest 2 continues to have an impact with ongoing post-study collaborations and published analyses. This study not only helped improve treatments but also strengthened Malaysia's standing in the global ophthalmology research community.



Datuk Dr Nor Fariza Ngah in her office

What makes Malaysia a strong player in clinical research?

Malaysia's diverse patient population is one of our greatest strengths. Our research findings are applicable to multiple ethnic groups worldwide, making us an attractive destination for industry-sponsored trials.

We also have strong governance and an ethical research culture, ensuring that our research meets international standards. However, I believe there is still room for growth, particularly in early-phase and investigator-initiated studies.

What is your vision for the future of Malaysia's research ecosystem?

Looking ahead, I want Malaysian clinical research to gain greater global recognition. When I started, Malaysia wasn't known for retina research. Now, global studies actively invite us to participate.

To gain recognition, we need to be seen. Presenting our work at global conferences builds credibility and opens doors for future collaborations.

At the same time, I believe in stepping back to let the next generation lead. Research is about building a legacy and it's important that younger researchers continue the work and take it further.

RISING STARS IN CARDIOLOGY

Cardiology stands as one of Malaysia's top 3 therapeutic areas in sponsored research, with over 240 studies conducted since 2012. This remarkable progress reflects the dedication and expertise of our investigators and healthcare professionals working tirelessly to improve outcomes for heart patients. In this section, we spotlight rising stars in cardiology, whose commitment and contributions continue to strengthen Malaysia's role in advancing cardiovascular research on the global stage.

Dr Kamaraj Selvaraj

Senior Consultant Cardiologist

Sultan Idris Shah Hospital, Serdang



Areas of Interest in Research

Interventional cardiology

With over a decade of experience, I specialize in interventional cardiology, focusing on peripheral and structural heart interventions. My passion lies in refining life-saving procedures and expanding treatment options for cardiovascular patients.

As the current Chair of the Interventional Cardiovascular Society of Malaysia (ICSM), I am committed to advancing Malaysia's role in cardiovascular research and innovation. I have led multiple international clinical studies as a Principal and Co-Principal Investigator and actively contribute to global cardiology conferences.

I earned my MBBS from Calicut University and MRCP from Ireland, with additional training in TAVI, TEVAR, and EVAR across Taiwan, Thailand, and India. In recognition of my contributions, I was awarded the Fellowship of The National Heart Association of Malaysia (FMHAM) in 2017, the Fellowship of The Society of Cardiovascular Angiography and Interventions (FSCAI) from the US in 2018, and the Fellowship in ASEAN College of Cardiology in 2021.

Beyond clinical practice, I serve as an honorary lecturer and mentor, working towards making Malaysia a centre of excellence for both in-house and international clinical research.

Dr Diana Foo Hui Ping

Senior Research Medical Officer & Director of the Human Physiology Laboratory CRC

Sarawak General Hospital



Areas of Interest in Research

Cardiovascular disease prevention and early detection, echocardiography, cardiometabolic health, digital health solutions, and integrated care strategies.

As a clinician-researcher, I'm always fascinated by the intersection between science and patient care—where discoveries are translated into real-world applications that improve lives.

My journey began in 2013 at the CRC, Sarawak General Hospital. Back then, research in Malaysia was still in its infancy. There were no clear roadmaps—just challenges that demanded persistence and adaptability. I had to quickly build skills in echocardiography, manage research projects and grow networks, all while charting a non-traditional path as a young doctor in the Ministry of Health.

Over the years, I've led and contributed to local and international studies, secured major research grants and transformed our Human Physiology Lab into a MedTech research hub. My passion remains rooted in bridging the gap between science and patient care—especially in areas like cardiovascular prevention, diagnostics and digital health.

Beyond achievements, I believe in the power of mentorship, collaboration, and early intervention. Research is not just about data—it's about listening to patients and turning insights into better futures.

Dr Kantha Rao Narasamuloo

Consultant Cardiologist & Electrophysiologist

Sultanah Bahiyah Hospital



Areas of Interest in Research

Catheter ablation and cardiac implantable devices

My journey in medicine began with an MBBS from the Manipal Academy of Higher Education, India, followed by Membership from the Royal College of Physicians (MRCP), United Kingdom. To further refine my expertise, I pursued a fellowship in Cardiology, before subspecialising in cardiac Electrophysiology at Christchurch Hospital, New Zealand.

My commitment awarded me with Excellence in Service Awards (2010, 2013, 2017) and honours such as Pingat Jasa Kebaktian (PJK) and Ahli Mahkota Kedah (AMK). I have collaborated with UNIMAP and Sunway University for research and innovations which has been published in International Journal of Integrated Engineering, Chemosphere, ITEX and won few prestigious awards for the category of innovation.

Beyond clinical practice, my cardiology research been published in esteemed journals such as the International Journal of Cardiology, Journal of the American College of Cardiology & Journal of Arrhythmia. My research interests focus on cardiac arrhythmia, with several of my procedural outcome been shared at international conferences.

I am committed to advancing cardiac electrophysiology in Malaysia and continuously strive to enhance patient care through research, innovation, and clinical excellence.

Dr Muhammad Izzad Johari

Consultant Cardiologist & Electrophysiologist

Sultanah Nur Zahirah Hospital



Areas of Interest in Research

Preventive cardiology, heart failure, and cardiac electrophysiology.

With a deep-rooted passion for cardiology, I embarked on my medical career with an MBBS from the University of Malaya (UM) in 2009, followed by a Master of Medicine in Internal Medicine (M.Med Int. Med) from Universiti Sains Malaysia (USM) in 2017. My dedication to cardiovascular health led me to specialise in Cardiology, with further training in Electrophysiology to refine my expertise in managing complex arrhythmias.

My journey in clinical research began in 2019, where I have since been actively involved in sponsored studies focusing on heart failure, arrhythmia management & cardiac devices. My research has been presented at both national and international conferences, reinforcing my commitment to advancing Malaysia's footprint in global cardiology research.

Beyond research, I am driven by a mission to enhance electrophysiological treatments, integrating innovation & evidence based practices to improve patient outcomes. Collaboration and continuous learning remain at the heart of my approach as I strive to elevate cardiovascular care.

“Beyond research, I am driven by a mission to enhance electrophysiological treatments, integrating innovation & evidence based practices to improve patient outcomes.”

Dr Muhammad Izzad Johari

Dr Dharmaraj Karthikesan

Interventional Cardiologist
& Director, Invasive Cardiac
Catheterization Laboratory

Sultanah Bahiyah Hospital



Areas of Interest in Research

Coronary interventions, particularly left main intervention and chronic total occlusion (CTO)

In 2012, my father passed away suddenly from cardiac arrest in Alor Setar. Since then, my goal has been to develop a public cardiac centre of excellence in Northern Malaysia—one that delivers evidence-based, patient-centred care and advanced interventions, backed by strong research.

I graduated from UNIMAS, obtained my MRCP (UK) and trained in interventional cardiology at the Central Chest Institute of Thailand. I currently serve at Hospital Sultanah Bahiyah, where I was appointed as Malaysia's youngest Director of an Invasive Cardiac Catheterization Lab in 2019. Despite limited resources, we transformed our centre into a high performing complex coronary intervention unit within a year.

In 2024, I completed my MSc in Clinical Trials at the University of Oxford with an ESC grant—my most significant milestone. I'm passionate about embedding clinical trials into routine care and removing barriers to recruitment, especially for busy clinicians. Malaysia needs more RCTs in coronary intervention, and with our capable operators and patient volume, we're ready to lead. I'm grateful to Clinical Research Malaysia, especially Dr. Akhmal, for supporting the setup of my trial.

Dr Foo Jhi Hui

Consultant Cardiologist &
Electrophysiologist

Queen Elizabeth II Hospital



Areas of Interest in Research

Atrial Fibrillation, Cardiac Physiological Pacing, Remote Monitoring, AI-Assisted ECG Diagnosis, Genetic Studies in Cardiac Rhythm Disorders

As a Consultant Cardiologist and Electrophysiologist at HQE II, I oversee cardiac device implantation and ablation services while actively contributing to research and training. I am a Fellow of the Heart Rhythm Society (FHRS) and a Certified Cardiac Device Specialist (CCDS, IBHRE 2022). My expertise lies in cardiac physiological pacing and atrial fibrillation ablation, and I have trained doctors from Malaysia, Vietnam, the Philippines, and Indonesia.

My research journey began in 2018, leading to presentations at ESC 2019 and pioneering a pilot study on rheumatic heart disease screening. As the primary investigator for the Brugada syndrome genetic study, I achieved 150% enrollment in early 2024. I also led the Librexia AF study, completing full patient recruitment.

Passionate about advancing electrophysiology, I focus on new anticoagulant therapies, AI-assisted ECG diagnosis, and remote patient monitoring. I hope to expand research beyond the National Heart Institute (IJN) to include Ministry of Health hospitals, ensuring broader participation in studies on genetic cardiomyopathies, artificial intelligence and next-generation cardiac devices to improve patient care.



In 2012, my father passed away suddenly from cardiac arrest in Alor Setar. Since then, my goal has been to develop a public cardiac centre of excellence in Northern Malaysia - one that delivers evidence-based, patient-centred care and advanced interventions, backed by strong research.



Dr Dhamaraj Karthikesan

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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

Tengku Ampuan Afzan Hospital



Hospital Tengku Ampuan Afzan (HTAA) has come a long way since its early days as Rumah Sakit Kuantan in 1904. Located on a 40.1-acre site in the heart of Kuantan, it began as a modest facility with wooden buildings and thatched roofs. Overseen by British medical staff, including Dr. Frazer, it played a crucial role in the early development of modern healthcare in Pahang. During the Japanese occupation, Dr. Mohamad Said, a local physician, ensured the hospital remained operational, serving both civilians and war victims.

Following Malaysia's independence in 1957 and the relocation of Pahang's capital from Kuala Lipis to Kuantan, the hospital was elevated to general hospital status. This marked the beginning of its transformation into a more comprehensive healthcare centre. Over the decades, wooden structures gave way to permanent stone buildings, and services expanded to meet the region's growing medical needs.

The hospital's modern chapter began on 3 November 1995, when Sultan Ahmad Shah officiated its new building and renamed it in honour of his consort, Tengku Ampuan Afzan. Today, HTAA stands as a leading healthcare institution in the East Coast, offering a wide range of specialties including cardiology, oncology, nephrology, and respiratory medicine.

With a strong commitment to accessible and quality care, HTAA continues to serve as a crucial medical hub for Kuantan, Pahang, and neighbouring states—balancing its deep historical roots with modern medical advancements.



LIST OF THERAPEUTIC AREAS

- Anaesthesia & Intensive Care
- Clinical Research
- Dermatology
- Emergency & Trauma
- Forensic Medicine
- General Medicine
- General Surgery
- Nephrology
- Neurology
- Neurosurgery
- Obstetrics & Gynaecology
- Ophthalmology
- Oral Surgery (Dental)
- Orthopaedics & Traumatology
- Otorhinolaryngology (ENT)
- Pathology
- Paediatrics
- Psychiatry
- Radiology
- Rehabilitation
- Respiratory Medicine
- Urology

HTAA TEAM


1,032
Doctors


116
Pharmacists


885 Beds


1,459
Nurses


739
Total No. of Staff


1.67mil
Population Served
source: Department of Statistics Malaysia, census 2024

ABOUT CLINICAL RESEARCH CENTRE, HTAA

The Clinical Research Centre (CRC) at Hospital Tengku Ampuan Afzan (HTAA) was established in 2003 with the goal of promoting research at both the hospital and national levels, within the broader Network of Clinical Research Centres. This initiative aligns with the Ministry of Health Malaysia's objectives to foster high-quality research projects. The committee overseeing the CRC at HTAA was formed in 2003, while the official CRC office began operations on 23 March 2016.

The CRC HTAA plays a key role in supporting clinical research and clinical trial projects in collaboration with the CRC network across Malaysia. Its primary mission is to create an environment conducive to conducting high-quality, ethical clinical research that leads to tangible improvements in patient outcomes at HTAA, Kuantan.

Total headcount of CRM staff at Hospital Tengku Ampuan Afzan including Associate Regional Manager (ARM): 15 staffs



Date: Dr Zainal Ariffin bin Omar, Pahang State Health Director, officiating the launch of the new CRC office by signing the commemorative plaque at the Pahang Clinical Research Centre on 23 March 2016.



Standing from L-R: Nur Belgii, Noor Sami'ah, Suriani, Nur Lijana, Nur Ezzati Fatin, Fatima Diyana, Zati Nabillah, Siti Aisyah, Nur Hanisah

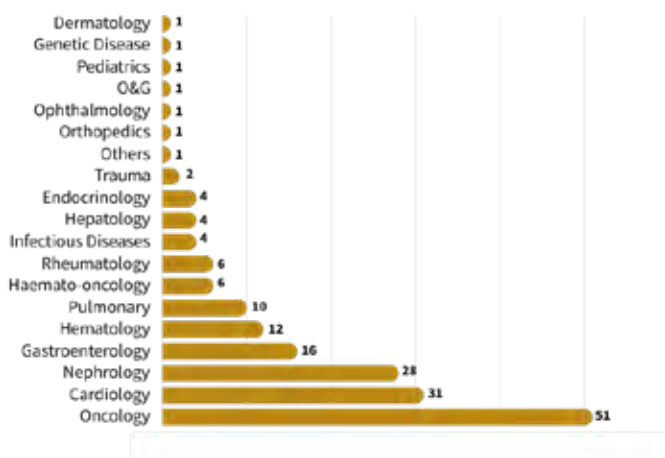
Sitting from L-R: Nur Faatihah, Syafiqah Hanani, Mohd Aliman, Murniyati, Tazah 'Atina, Nor Naimah Sa'idah



SNAPSHOT OF SPONSORED CLINICAL RESEARCH ACTIVITIES IN HTAA (2014 -2025)

Awarded	187
On-going	54
Recruiting	33
Start-up	16
Closed/Completed	38
Terminated/Withdrawn	8

ISR BY THERAPEUTIC AREAS



ACCOMPLISHMENTS IN CLINICAL RESEARCH

Year	Accomplishment
2023	First Recruiter in Malaysia for Ocular Hypertension Study Protocol: TO-01C101 (OASIS)
	First Patient Enrolled Globally for Non-Small Cell Lung Cancer Study Protocol: D5162C00052 (OSTARA)
	First Subject Randomized in Malaysia for Pulmonary Arterial Hypertension Study Protocol: INS1009-203
	First Patient Randomized in APAC for Non-Small Cell Lung Cancer Study Protocol: D5162C00048 (TARGET)
	First Subject Randomized in Malaysia and 3rd Globally for Lupus Nephritis Study Protocol: CLNP023K12201
	Global 3rd Recruiter for Cohort 1 in IgA Nephropathy Study

MEET OUR TEAM

Faizah Binti Harun *Associate Regional Manager, Northern A1*

Team CEO Award 2022 Recipient.



About My Role

I am Faizah Harun, the CRM Associate Regional Manager for Northern A1 at Hospital Pulau Pinang (HPP), where I oversee oncology trials. The oncology department at HPP is supported by 14 CRM Study Coordinators (SCs). I have been with CRM since 2015, and this year marks my 10th anniversary with the organization. My role involves managing, supervising subordinates and ensuring the smooth, effective, and high-quality conduct of clinical trials at the site. To achieve this, I collaborate closely with SCs, investigators, CROs, sponsors, and other stakeholders to oversee trial activities and provide support whenever required.

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

When I started as a Study Coordinator, my days were spent managing patient visits and ensuring everything followed trial protocols. While mentally demanding, the strength and resilience of our patients were constant reminders of why this work matters. Their determination inspired me to fully support them throughout their time at the site.

Clinical research has shown me the incredible impact of medical breakthroughs that was made possible by dedicated teams, accurate data and strict ethical standards. As the field evolves, staying current with new knowledge and skills is essential to ensure we continue advancing healthcare in meaningful ways.

What has been your greatest learning opportunity in clinical research?

Being part of clinical research has taught me the immense value of collaboration and communication among study team members. The dynamics in clinical research are unique, as every individual plays a crucial role in determining the success of the study. Ultimately, everyone works together toward a common goal. In my current role, I also focus on people management, emphasizing the importance of teamwork and recognizing

the value of diverse perspectives among team members.

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

Being approachable and open to communication has been invaluable in supporting my current role. It allows me to build closer relationships with my subordinates, investigators at the site, and the study team, making them feel more comfortable—even during difficult conversations. This fosters an environment of openness and transparency. Additionally, my resilience enables me to turn conflicts into opportunities, quickly recover from challenging situations, get back on track, and embrace change.

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

My colleagues have been a big source of motivation at work. Having supportive and understanding subordinates at the HPP site is truly a blessing. We work as a team and help each other whenever needed. Additionally, the trust placed in me drives my sense of responsibility and motivates me to give my best for the CRM team.



Pulau Pinang Hospital Team

Puteri Nur Aliah Binti Wan Faizal
*Human Resource Development
 Corporation-accredited trainer*



Roles and Responsibilities

Hello, my name is Puteri Nur Aliah Binti Wan Faizal, an HRD Corp-accredited trainer with a strong passion for empowering professionals in the clinical research field. I lead the development of CRM's self-learning hub, ensuring it provides continuous education and skill-building for Study Coordinators. I also train Provisionally Registered Pharmacists (PRPs), organise NJ training programmes and deliver GCP refresher courses tailored to industry needs. Additionally, I actively contribute to the Centre of Excellence, supporting high standards in clinical research education and training.

Can you share your journey in the clinical research field & what led you to this role?

My clinical research journey began as a study coordinator managing oncology trials at Hospital Kuala Lumpur. I led cancer studies, ensured protocol compliance, and participated in site audits and sponsor presentations. These experiences sparked my passion for training and mentorship, highlighting the importance of well-trained coordinators. This led me to transition into a trainer role, where I now focus on developing learning programmes and guiding future clinical research professionals. It's been a fulfilling journey, and I'm proud to support the industry's growth.

What important skills and knowledge do you focus on teaching in the CoE Foundation Programme?

At the Centre of Excellence, I focus on equipping trainees with the skills and knowledge to excel as study coordinators, emphasizing GCP compliance. I combine regulatory understanding with practical application, fostering critical thinking, problem-solving and communication. Through interactive discussions and real-life scenarios, I aim to create a supportive environment where trainees can confidently grow and become ethical professionals in clinical research.

What are some of the biggest challenges in training new study coordinators?

Training new study coordinators is challenging due to their limited exposure to clinical research. Many come in with a little background in the field, so I focus on building a strong foundation and simplifying complex regulations through hands-on learning. Confidence, especially in interactions with

investigators and regulatory bodies, is another key hurdle. I foster a supportive environment through mentorship and role-play to enhance communication and problem-solving skills. "My goal is not just to train but to empower them with the confidence and knowledge to thrive in their roles."

Have you encountered any memorable moments or success stories from past trainees?

One of the most rewarding parts of being a trainer is seeing my trainees grow. Despite coming from different backgrounds, they bond through activities and stay in touch, sharing their progress. The most memorable moments are when they confidently present their final outcomes, showing how far they've come. Their transformation is what makes this journey meaningful.

What drives you in your day-to-day work—perhaps a strong team, impactful outcomes or even something as simple as coffee?

What motivates me daily is seeing my trainees grow in understanding, confidence & passion for clinical research. Knowing I help shape the next generation of study coordinators keeps me going. I'm also lucky to work with an amazing trainer, Syifa Mazlan, whose dedication, experience and support make every challenge easier. Together, we strive to create the best learning experience. And of course, seeing our trainees succeed—and a good cup of green tea—keeps the enthusiasm flowing!



Puteri and her colleague, Nurul Syifa Binti Mazlan

CONTRIBUTION

Recruitment Of Ulcerative Colitis, A Less Common Disease Into Clinical Trial In Malaysia

Author: Ng Shu Hui, Senior Site Manager, Johnson & Johnson (Global Clinical Operations), Malaysia

Each year on 19 May, World Inflammatory Bowel Disease (IBD) Day is observed, uniting individuals across the globe in raising awareness and support for those living with Crohn's disease (CD) and Ulcerative Colitis (UC). Both UC and CD are chronic inflammatory conditions of the gastrointestinal (GI) tract—UC primarily affects the large intestine or colon, whereas CD can involve any part of the GI tract.

Imagine living with a constant, urgent need for frequent bowel movements at the most inconvenient times—sometimes accompanied by bloody stools. For individuals with IBD, daily life can be a struggle, not only due to physical symptoms but also the psychological burden that accompanies the disease. Treating IBD is therefore not solely about symptom management, it's about improving quality of life and helping patients maintain a sense of normalcy amidst these daily challenges.

In Malaysia, access to advanced therapies can be limited in certain hospital settings. This is where clinical trials play a vital role, providing patients with access to novel treatments and high-quality care. In this article, I would like to highlight the remarkable recruitment efforts for a UC trial in Malaysia—despite UC being a relatively uncommon condition in the country.

Three Malaysian hospitals were selected to participate in a company-sponsored clinical trial targeting patients with active moderate to severe UC. Recognising the nature of the disease and its rarity, early recruitment strategies were adopted. An advertisement for the UC trial was launched promptly upon receiving regulatory approval, in collaboration with Clinical Research Malaysia (CRM)'s Business Relations team. This proactive approach led to several patient referrals.

Beyond that, investigators contributed significantly to recruitment by securing referrals, engaging with disease support groups, and taking the time to explain treatment options—including the benefits and risks of participating in a clinical trial. These collective efforts led to the successful enrolment of 13 patients within a 7-month recruitment period. Notably, Hospital Sultanah Aminah (HSA) was recognised as the global top-recruiting site—tied with a site in Poland. This impressive milestone reflects the strong collaboration between CRM, the sponsor, and all participating sites.



Photo taken at Sultanah Aminah Hospital, Dr Firdaus - Principal Investigator (sitting), Dr Selva - Main Sub-Investigator (top right), and Ms Rainianti - Main Study Coordinator (top left)



Case presentation by SC from HSA (Rainianti) during the simulation meeting at Aloft hotel.

We firmly uphold the belief that patients are waiting—and that we must accelerate access to the best available treatment options.

The challenges, however, do not end with patient recruitment. Continued care and commitment from investigators remain crucial throughout the trial. Study coordinators, too, play an essential role—juggling patient schedules, data entry, drug shipments, biological sample management, and more. Nevertheless, the participating hospitals have demonstrated their capacity to manage these responsibilities effectively, paving the way for continued excellence in clinical research.

A special acknowledgement goes to the dedicated team at Hospital Sultanah Aminah (HSA), where the main sub-investigator, Dr Selva, screened the first patient just one day after site activation—followed by several more within the first 1–2 months. The study coordinator, Rainianti, managed the study logistics impressively well despite being new to IBD trials. Being the second site globally to screen a patient is no small feat!

While gaining recognition for their efforts, the HSA team also encountered numerous challenges during the enrolment journey, including strict eligibility criteria outlined in the sponsor's protocol and technical issues related to study equipment and systems. Nonetheless, they remained resilient. Consistent feedback was provided to the sponsor for continuous improvement—helping to pave the way for future patients. The HSA team truly rose to the occasion and delivered outstanding results.

We would also like to express our sincere gratitude to all trial personnel involved in this UC study. This includes, but is not limited to:

- University Malaya Medical Centre – Prof Ida Hilmi, Lorraine
- Hospital Sultanah Aminah – Dr Firdaus, Dr Selva, Rainianti
- Hospital Sultan Idris Shah – Datuk Dr Rosaida, Faizah

Each of these individuals played a vital role in achieving Malaysia's total recruitment target and contributing to the advancement of IBD clinical trials in the country.

In addition to recruitment efforts, a collaborative initiative between the Sponsor, CRM, and participating sites was introduced to improve the overall patient experience and trial conduct. Through this initiative, trial patients are able to receive care at a nearby clinic and have their therapies delivered directly to their doorstep.



Successful launch of the Local Care Model on 31 May 2024 at Aloft Hotel, Malaysia. The event was joined by esteemed Investigators – Prof. Ida (UMMC), Dr. Selva (HSA), and Datuk Dr. Rosaida – along with the CRM management team (Hafiza, Intan, Jurina), CRM SC/MHP representatives (Rainianti, Nazulia, Farahin, Faizah) and the J&J team (EeLaine, WeiQuan, Shu Hui, Lijen).



Ice breaker among the Mobile Healthcare Professionals

Malaysia: The Hub for Medical Device Trials

Journal for Clinical Studies, Volume 17, Issue 1

Authors: Koh Liew Eu, Cheng Shu Hui, Nur Ain Amir, & Nur Aziemah Abdul Ghani

Over the years, medical device has undergone significant transformation, with the use of evolving technological tools such as artificial intelligence (AI), machine learning (ML) and Internet of Things. In Malaysia, all medical devices are required to be registered with the Medical Device Authority (MDA), in compliant to the Medical Device Act 2012 (Act 737), before placing in Malaysian market. As for medical device clinical trial, a Medical Device (Exemption) Order 2016 grants exemptions from registration for medical devices designated for clinical investigations or other clearly specified purposes. Through medical device clinical trials, the safety, effectiveness, and performance of the devices could be evaluated before approval for general use and in post-marketing evaluations.¹ While pharmaceutical trials take up the largest share of trials conducted in Malaysia, the potential for medical device clinical trials is an opportunity to be tapped into, particularly with the current robust clinical trial ecosystem in the country. Therefore, this article will be discussing on the current landscape and future outlook of medical device trials in Malaysia.

Regulatory Overview

Medical devices that are intended for clinical investigational use (CIU) or clinical research use (CRU) must follow the process of notification of exemption from Registration of Medical Devices. The review timeline for CIU and CRU is approximately 30 and 14 working days respectively, yet it is important to ensure that all assessment data and required documents are completely compiled according to the guidance document for a successful application. All medical device trials follow the same pathway.²

Malaysia's Medical Device Clinical Trials Landscape

Malaysia's diverse healthcare landscape presents extensive opportunities for conducting clinical trials across a wide range of therapeutic areas. Based on Figure 1, a total of 46 interventional medical device trials were conducted in the last 6 years.³ Cardiology/vascular diseases stands out as the leading area, with 18 medical device trials (Figure 2) contributed by the volume of innovations addressing cardiovascular health which is a critical focus in global healthcare, could provide vital data

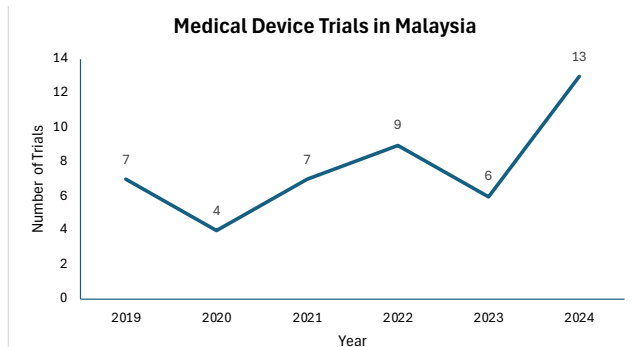


Figure 1: The graph shows the number of industry-sponsored interventional medical device trials in Malaysia over a span of six years (2019–2024) (Source: CRM Annual Report from 2019–2023 and CRM Database).

during feasibility assessments. The integration of Electronic Medical Records (EMR) within hospitals supports investigators in providing real-time patient pool for a certain disease condition, further translating to a more reliable recruitment projection that ultimately meets the recruitment targets set.

These trials were conducted across multiple sites in the public, private and academic centres which are staffed by experienced principal investigators and supportive study team as well as being well-equipped thus ensuring clinical trial are delivered with speed, quality and reliability.

The National Heart Institute has conducted various clinical trials for medical devices, having participated in over 10 trials, including those focused on coronary stents, heart valves, as well as a first-in-man trial.⁴ Hospitals in the public sector such as Pulau Pinang Hospital, Queen Elizabeth II Hospital and Sultan Idris Shah Hospital have also participated in multi-regional clinical trials in which the data generated was used for regulatory submissions.

In this day and age, the incorporation of artificial intelligence (AI) into medical devices has completely transformed the healthcare sector by increasing diagnostic precision especially in early disease detection. As an example, the successful identification of Malaysia's first lung cancer case was identified using AI which saw the public and private partnership between a local organisation with global pharmaceutical company.⁵ This accomplishment highlights how AI medical device will continue to evolve, presenting various opportunities for patients and healthcare professionals in the country to tap into.

Malaysia at the Forefront of Clinical Trials

The recently published IQVIA report "Rethinking Clinical Trial Country Prioritization" highlights Malaysia as a promising destination for medical device clinical trials due to its diverse patient population, strong regulatory framework, including streamlined processes for unregistered devices, advanced healthcare infrastructure and experienced clinical workforce.

Positioned in the Opportunity Tier alongside other Southeast Asian countries like Thailand, Vietnam, and Indonesia, Malaysia offers significant potential for patient intensive trials with minimal concerns about trial saturation. The report also ranks Malaysia among the Top 30 globally and leading in Southeast Asia for clinical trial readiness. Moreover, Malaysian clinical investigators have also been recognised by the clinical research industry as top and first global/regional recruiters in multiregional clinical trials.⁶

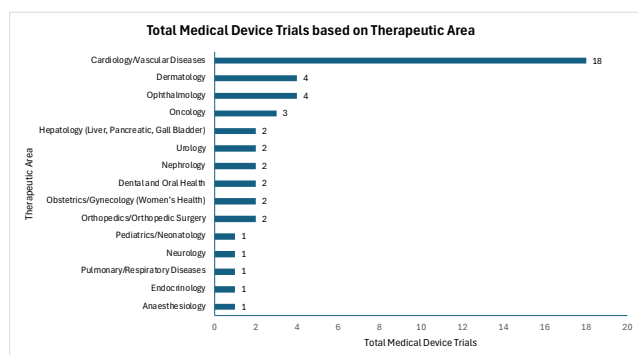


Figure 2: The bar graph illustrates the distribution of industry-sponsored interventional medical device trials based on various therapeutic areas from 2019 to 2024.

The establishment of Clinical Research Malaysia (CRM) as a global trusted research management organisation has also significantly shaped the clinical research landscape in the country. CRM as the national one-stop centre and site management organisation for the Ministry of Health has also been recognised in an article by Syneos Health for its contribution in driving the clinical research agenda of the country as well as delivering quality trials from global sponsors.⁷ Together with a robust regulatory framework, streamlined clinical trial process and well-equipped infrastructure at trial sites, Malaysia is being viewed as the hub for global clinical trials. Malaysia is emerging as a dynamic hub for medical device trials with forward-thinking regulatory initiatives. MDA has outlined the "Innovative Medical Device Pathway Framework" to foster innovation and streamline the regulatory process for medical devices to be applied soon. This framework, which will be implemented soon, comprises two main initiatives. Initiative 1 is the Innovative Devices Review Service which provides guidance on safety and performance principles for devices at varying development stages. It includes two components: Initiative 1A - Early Development Review and Initiative 1B - Pre-commercial Review. Next, Initiative 2 complements the Initiative

1B - Pre-Commercial Review pathway by offering two key components: a facilitated Registration Exemption Notification for clinical investigations, and a compliance conclusion letter from MDA. This strengthens funding applications to the National Technology & Innovation Sandbox (NTIS) under the Ministry of Science, Technology and Innovation (MOSTI). Malaysia's national sandbox programme allows for relaxed regulatory framework in which medical device trials can be conducted. MDA can also act as the sandbox coordinator for applicants to gather essential safety and performance data during clinical trials. In a nutshell, the entire framework is an intervention strategy to assist researchers in novel R&D development of medical devices by offering early regulatory knowledge input and support the growth of Malaysia's medical device sector.⁸

An opportunity to align with global trends in medical devices specifically in AI/ML, lies in streamlining international standards, enabling faster approvals and facilitating smoother global operations. Medical device clinical trial regulations differ significantly across countries, reflecting varying risk classification systems, approval pathways, and monitoring mechanisms. FDA provides detailed guidance for high-risk devices, including specific frameworks for Software as a Medical Device (SaMD)⁹ and AI/ML technologies, with premarket review process like Premarket Clearance, De Novo Classification and Premarket Approval (PMA).¹⁰ Apart from the current regulatory process of general medical devices, MDA may adopt detailed SaMD and AI/ML specific frameworks and harmonise regulations or the process for assessment and supervision of clinical trials to increase efficiency, foster innovation, and ensure safety in medical device clinical trials. Adopting AI/ML-specific regulatory frameworks alongside general medical device regulations can address unique risks like algorithms error and biases, ensuring patient safety, streamlines updates and builds trust while aligning with global standards to enhance competitiveness and regulatory efficiency. With these benefits and advantages, Malaysia can position alongside other leading nations in embracing and advancing the latest trends in medical devices on the global stage.

Conclusion

Malaysia has immense potential for medical device clinical trials. This potential is driven by its matured clinical trial ecosystem, skilled professionals, robust regulatory framework and supportive government policies. Initiatives like the Innovative Medical Device Pathway Framework and support from Clinical Research Malaysia demonstrate the country's commitment to foster innovation and maintain high trial standards. To realise its full potential, Malaysia may focus on regulatory harmonisation, adoption of advanced frameworks for emerging technologies, and collaboration between researchers and clinicians. By building on these strengths, Malaysia can drive advancements in medical device research, contributing significantly to global healthcare innovation.

Acknowledgement

We would like to express our sincere gratitude to Puan Nur Syafura Binti Ariffin from the Clinical Investigation (CI) section of MDA, Ts. Zubair Faramir Zainul Fadziuddin and Puan Idamazura binti Idris Harun, both from the Policy & Strategic Planning Division of MDA, for their inputs during the development of this article.

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CRM IN PHOTOS



CRM with MSD team led by Clinical Research Director, Ms Luisi Khalil.

8
Jan



CRM met with Tigermed regional team.

17
Jan



CRM met with Diabetes Malaysia.

13
Feb



CRM with the Sandoz team led by Mr Carlos Patarrana, Country Head of Malaysia, Brunei & Singapore

12
Feb



CRM with Ms Nicole Lee, Development Operations Senior Manager at Amgen along with IQVIA representatives, Ms Lydia Paul, and Ms Chin Chin Yeoh

26
Feb



CRM 1st touchbase of 2025 meeting with the J&J Global Clinical Operations team.

27
Feb



CRM with PSI CRO representatives, Dr Katarzyna Moscicka, Head of Feasibility, Mr Barrie Koh, Head of APAC and Mr Wuthichai Sithivanich, Clinical Operations Manager of SEA.

7
Mar



CRM 1st touchbase meeting of 2025 with the AstraZeneca team

14
Mar



CRM with the ECRI team led by Mr Matthew Chan, Associate Director of Business Development.

24
Mar



CRM with Deloitte team.

8
Apr



Meet with Novo Nordisk team, led by Head of Clinical Development Center, Samiran Maity

10
Apr



CRM with Clinical Research Director, Dr Carren Teh & Dr Lee Pei Jia (ICR)

28
Apr

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