

BY CLINICAL RESEARCH MALAYSIA

# CRM Bulletin

ISSUE 26 | Jul - Dec 2023

## EXCELLING IN EARLY PHASE CLINICAL TRIALS

### RESEARCH PERSONALITY

Dr Veena Selvaratnam

### RISING STARS IN RESPIRATORY MEDICINE

### FEATURED SITE

National Cancer Institute





# 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 Issue 26!

What a great way to cap of the last half of 2023.

Mid last year, CRM held its first strategic meeting, envisioning what's next in its path for the upcoming decade. Participated by the Board of Directors and Management of CRM, the meet was focused on developing key missions and strategies to be delivered between 2023 -2033, after having forecasted the market growth of clinical research in Malaysia based on global trends and current developments. We have targets to accomplish together by 2033 and are confident that we are progressing well and on track towards making Malaysia the preferred clinical research hub in the region.

It's been truly a busy yet productive time for CRM these 6 -months, with multiple engagements and discussions held with our stakeholders and partners. We held our first Inter-Agency Roundtable Discussion, which saw the coming together of relevant government agencies across ministries, in an effort towards propelling clinical research as a recognised valued investment to the country. We've also had multiple international meets, most significant was during ESMO Madrid and the Global Partners Program by Princess Margaret Cancer Centre in Canada. Along with the presence of Ministry of Health's Head of Oncology Service, these discussions had made a profound impact to some of the industry leaders, which has led towards positioning more trials to Malaysia, including First-in-Human studies.

Talking about early phase studies, we have hit significant milestones in this front, starting with the initiation of the first FIH study at Hospital Ampang led by Dr Veena Selvaratnam and team. In addition, investigator Dr Voon Pei Jye made news for having co-authored the FIH study presentation in the EORTC, AACR & NCI Meeting at Boston. It was truly gratifying to read Sarawak General Hospital along the likes of world-class institutions like Memorial Sloan Kettering and Dana Farber Institution!

Capping the final leg for 2023 is Malaysia's own accomplishment in achieving its highest number yet in new sponsored research, with 276 studies, 25% above the target for the year! It's truly a remarkable achievement, and much gratitude goes to our investigators, study team, ethics committees, regulatory authorities, and our industry members for their significant role in enabling this progress.

Reflecting on the remarkable strides made in 2023, CRM is reminded of the profound impact of collaborative efforts in clinical research. Research contributions from every one of us today open the door to better tomorrows. Every effort, from forming partnerships to taking the lead on innovative projects, has brought us one step closer to realising our goal of making Malaysia as a preferred hub for clinical research in Asia. We are grateful to everyone who has contributed along the way and are eager to keep working towards our vision. Together, we're shaping a healthier tomorrow.

**Dr. Akhmal Yusof**  
CEO, Clinical Research Malaysia

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## CRM GUIDING PRINCIPLES



### HUMANITY

Address unmet medical needs, access to innovative treatments and transform health outcomes for patients through clinical trials

### STABILITY

Excellent and consistent performance to deliver with speed, reliability & quality



### SUSTAINABILITY

Create business sustainability through core values, code of conduct & operational excellence



# 2033 VISION

To be the preferred hub for  
clinical research in Asia

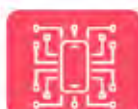
## MISSION



Global Trusted Research  
Management Organisation



Clinical Research  
Professions Development



Digitalise  
Processes

## KPI 2023 -2033



# HIGHLIGHTS



## DIA CoRE Singapore Annual Meeting

**12 - 13 July 2023** – CRM as part of the DIA-CoRE Singapore Annual Meeting Programme Committee was present at the DIA CoRE Singapore Annual Meeting. The conference showcased recent trends in innovations launched in Asia with the rapid development of global economic growth in line with the remarkable achievements in healthcare and pharmaceutical.



## Protocol Compliance Workshop

**12 July & 22 November 2023** – CRM's Clinical Operations team held 2 Protocol Compliance workshops in the second half of 2023. The workshops are purposed for research teams to effectively manage protocol deviations and execute them in compliance with Good Clinical Practice.



## GCP Refresher Workshop

**20 July & 3 October 2023** – GCP Refresher Workshop plays a vital part in clinical trials as it provides not only public assurance that the rights, safety, and wellbeing of trial subjects are protected, but also ensuring that it is done with the best form of good clinical practice where one was conducted virtually and one at Tunku Azizah Hospital.



## MREC Good Submission Practice Workshop.

**9 August 2023** – MREC Good Submission Practice Workshop makes its comeback in 2023! The workshop organised by both CRM together with MREC & NMRR shared best practices to be implemented in submission of sponsored ethics application.



## National Regulatory Conference

**15 - 17 August 2023** – CRM was present at the National Regulatory Conference, which served as a platform to share the latest developments and innovations in the regulatory fields of pharmaceuticals and cosmetics.





## Nurturing New Talents in Sponsored Research

**8 September 2023** - CRM's Feasibility team successfully conducted the Nurturing New Talents (NNT) workshops, bringing diverse individuals such as investigators, research teams, medical officers, and nurses. The primary goal of NNT is to develop and grow the pool of investigators in clinical research.



## DIA Asia 2023

**13 September 2023** - CRM along with NPRA spoke at the DIA Asia 2023 in Beijing, sharing with the delegates in China on Malaysia's value proposition in clinical trials, regulations on CGTP, and outlining the vision for collaboration with partners in SEA to grow the market share of sponsored clinical trials in the region.



## I AM AWARE 2023

**18-19 September, 3 October & 21 - 22 November 2023** - CRM successfully managed another 3 I AM AWARE Roadshows (Sarawak General Hospital, Sultanah Nur Zahirah Hospital and Tuanku Ja'afar Hospital). With more roadshows, CRM aspires to pool a larger number of participants to enrol in clinical trials to become part of the noble agenda of developing new medicine and treatments for patients.



## Patient Recruitment & Retention Workshop

**19 September & 16 November 2023** - CRM's Patient Recruitment Specialist team conducted another 2 workshops to share patient recruitment and retention strategies to ensure delivery in trial participant enrollment.



## 16th National Conference for Clinical Research (NCCR)

**20 - 22 September 2023** - Aligned with its theme, "Quantum Leap in Research Leadership", the NCCR conference which was co-organised by CRM had delivered a program that was aimed in further exploring the boundaries of knowledge and innovation in the realm of clinical research. The conference hosted a lineup of esteemed speakers from various regions, including CRM-Named Lecture speaker Dr Joseph Cheriyan (Cambridge University, UK).



### 34th ASCOMOS Conference

**6 - 8 October 2023** - CRM attended the 34th Annual Scientific Congress of Malaysian Oncological Society (ASCOMOS), where oncologists and health professionals discussed the pursuit of better cancer knowledge in the era of personalized care, aligning with the theme "Scaling Greater Heights in Oncology."



### Training to Improve Performance of Study Coordinators Training

**16 - 18 October 2023** - CRM's Clinical Operation team conducts TIPS to enhance Study Coordinators' performance in clinical trials, implementing best practices to preserve and maintain their performance.



### ESMO Congress Madrid

**20 - 24 October 2023** - During the conference, CRM had several high-level engagements with global sponsors and CROs to promote Malaysia as a destination for clinical research in the region. Several Malaysian investigators were also recognized as co-authors in trials presented during the ESMO Congress.



### REACTA Forum

**16 - 17 November 2023** - CRM attended the REACTA Forum 2023, focusing on the evolving clinical research landscape in the digital age, under the theme "The New Era of Clinical Research".



### CRM Inter-Agency Roundtable Discussion

**20 November 2023** - CRM engaged with relevant agencies in the country to explore opportunities to work together, making the country an ideal location for investors in clinical research and thereby recognizing clinical research as a foreign direct investment.



### SIRIM Recertification

**23 November 2023** - CRM has successfully underwent SIRIM inspection, resulting with the continuation of ISO QMS 9001:2015 and ISO ABMS 37001:2016 certification. Impressive effort from CRM team for their diligent preparation and hard work!





## FERCAP International Conference 2023

**27 - 28 November 2023** - From plenary session to multiple parallel sessions, CRM was thrilled to participate and speak at the 23rd FERCAP International Conference in UMMC. The conference's tracks consist of clinical research opportunity, ethics & regulations challenges, big data in drug discovery and more, delivered by several speakers from various regions.



## Clinical Research Governance (CRGo) World Conference & International Clinical Trial Center Network (ICN) Symposium 2023

**29 November 2023** - The CRGo conference offered an excellent opportunity for fostering communication and knowledge exchange within research communities. During the event, CRM's CEO, Dr Akhmal Yusof presented on the opportunities in conducting clinical research in Malaysia and unveiled CRM's 10-year plan to establish the country being the preferred clinical research hub in Asia.



## ESMO Asia 2023

**1 - 3 December 2023** - Many Malaysian oncologists at ESMO Asia were named as co-authors in multiple abstracts. Dr Voon Pei Jye, Prof Ho Gwo Fuang, Dr Mastura Md Yusof and Dr Soo Hoo Hwoei Fen were invited speakers or discussants in mini oral sessions. Kudos to all our investigators!



## International Conference on Drug Discovery and Translational Medicine (ICDDTM) 2023

**5 - 6 December 2023** - ICDDTM aims to highlight the crucial role of science in advancing a nation's economy, especially in scientific research and innovations. A great opportunity for international and local investigator interested in clinical trials.

## NPRA Good Submission Practice Workshop

**12 December 2023** - In hopes of familiarising the industry members with the CTIL/CTX First In Human, CRM organised the NPRA Good Submission Practice workshop. Facilitating the workshop was Dr Zail, Head of Investigational Product & Safety Section in National Pharmaceutical Regulatory Agency, and team, who was there to address the essential aspects related to CTIL/CTX First in Human Submission practice.

# SPOTLIGHT FEATURE

## Malaysia Increasing it's Capabilities in Early Phase Clinical Research



**KUALA LUMPUR, 26 July 2023** - Clinical Research Malaysia (CRM) inked an education scholarship agreement with the Ministry of Health (MOH) and National Pharmaceutical Regulatory Agency (NPRA) earlier today at CRM headquarters. Under the agreement, CRM will be sponsoring two NPRA officers to pursue their Master's program in Clinical Pharmacology at King's College London.

The initiative is aligned with CRM's Phase 1 Realisation Project (P1RP) 2.0, which focuses on further enhancing Malaysia's capabilities on early phase/first-in-human trials. The project is an extension of the initial P1RP program launched in 2016 in which three NPRA officers and a Medical Oncologist from Sarawak General Hospital were sponsored for postgraduate studies and fellowship attachment respectively, at renowned global institutions, to build their expertise in early phase trials. Investment in human capital development is a continuous effort taken by CRM, an organization wholly-owned by the MOH, to ensure the country's readiness for safe and high-quality conduct of clinical trials.

Representing the organisations at the signing ceremony were Deputy Secretary-General Finance of MOH, Dato' Sri Norazman Ayob, Chief Executive Officer of CRM, Dr. Akhmal Yusof as well as NPRA officers Siti Norhayani Ismail and Fatin Diyana Fauzi. The sponsorship agreement was witnessed by YB Dr. Zaliha Mustafa, the Minister of Health and Rosilawati Ahmad, NPRA Director.

During the same program, YB Dr Zaliha also launched the Malaysia Decentralised Clinical Trial (DCT) Guidance Document. This guidance document is a first in Malaysia and will be an important step in aligning to the global trends of clinical trials where patient-centricity becomes more important, as well as adopting new and innovative clinical trial designs. The document was developed by clinical research stakeholders within the country and endorsed by the National Committee for Clinical Research.

# Malaysia Scores Big in International Oncology Conference



**10 November 2023** - Malaysia's clinical research fraternity accomplished global recognition, when several of the international clinical studies participated by Malaysian oncologists were featured in the recently held European Society for Medical Oncology (ESMO) Congress in Madrid, Spain.

Key highlights in the congress were the proffered paper presentations during presidential sessions, among which Dr Muthukkumaran Thiagarajan (Clinical Oncologist from Hospital Kuala Lumpur) and Dr Adlinda Alip (Clinical Oncologist from University Malaya Medical Centre) were named the co-authors in two Non-Small Cell Lung Cancer (NSCLC) studies. Both studies presented superior results of the respective trial treatment, establishing these treatments as first-in-line treatment for NSCLC with specific mutations.

Oncology research has been the focus of research and development of international pharmaceutical and biotech companies, comprising 38 per cent of global research programs and recording the highest expansion rate yearly compared to other disease areas. In Malaysia, approximately 20 per cent of over 2,000 sponsored research conducted are in oncology. Since 2021, CRM has enabled the setup of the early phase First-in-Human (FIH) clinical research ecosystem in Malaysia though the completion of its Phase 1 Realisation Project (P1RP).

This year, the country's first FIH study was conducted, involving a first-in-class trial therapy for patients with advance solid tumours. Findings from this study were featured in the AACR-NCI-EORTC International Conference 2023 in Boston last month, whereby Dr Voon Pei Jye, Medical Oncologist from Sarawak General Hospital became the first Malaysian to co-author a FIH global multicentre clinical trial, placing Malaysia alongside world top-ranking cancer institutes.

In addition to the engagements held in the ESMO Congress and other international meets, CRM also participated in the Global Partner Consultation Program organised by Princess Margaret Cancer Centre in Canada, which included the participation of Dr Ros Suzanna Ahmad Bustamam (Head of Service for Oncology and Radiotherapy, Health Ministry and Head of Oncology and Radiotherapy, Hospital Kuala Lumpur). With this year already breaking records of new trials recorded in the country (245 new clinical studies up till last month), CRM is steadfast in positioning Malaysia as the preferred hub for clinical research in the region.



# Clinical Research Provides Access to Innovative Therapies for Patients in Malaysia

**1 December 2023** - Malaysia has now over 2,200 sponsored clinical research conducted since 2012, with over 25,000 trial participants in these studies across different therapeutic areas, according to recent data inferred by Clinical Research Malaysia (CRM). Clinical Research Malaysia is a Global Trusted Research Management Organisation by the Ministry of Health that was given the mandate to catalyze sponsored research in the nation through building a robust clinical research ecosystem.

The Government of Malaysia recognized the value of clinical trials and has since built clinical research as an agenda within its 2010 National Economic Plan, lending to the establishment of CRM. The aim is to enable a facilitative ecosystem for global institutions (eg: pharmaceuticals, medical device companies and biotechnology companies) as well as the local industry to conduct clinical research in Malaysia.

The expansion of clinical research since CRM's formation has been especially impactful to patients enrolled in these studies. Close to 30% of the studies that were conducted in Malaysia are in cancer, cardiovascular diseases, and diabetes, which coincidentally are also the top three non-communicable diseases in Malaysia. Most importantly, these studies help address the unmet needs of the trial participants, especially in having early access to innovative investigative therapies when all other treatment options have been exhausted. The scope of patients that have access to these trials has been cast wide with many of the tertiary public hospitals, university hospitals and several private centers having clinical research conducted by respective institutions' clinicians.

The growth of global clinical research in Malaysia have been consistent since the establishment of CRM, especially with the last 4 years showing surplus growth annually. Activities in the past months saw CRM's engagements during ESMO (European Society for Medical Oncology) Congress that was held at Madrid, Global Partners Consultation program by Princess Margaret Cancer Centre in Canada, Regional Asian Clinical Trial Annual (REACTA) Forum in Chiba, Japan and Clinical Research Governance World Conference in Hong Kong, all aimed towards bringing impactful trials to Malaysia in addition to exploring collaborations that would further enhance Malaysia's clinical research capabilities, especially in early phase clinical research.

Besides the intangible benefit of addressing unmet needs of Malaysian patients, clinical research has also significantly contributed over RM 1 billion in Gross National Income since 2012 and created over 2,600 new skilled jobs in clinical research within the country. These coupled with Malaysia's track record for having delivered consistent performance in global clinical research through speed, quality & reliability has positioned the country as a strategic clinical research hub within the region.



# RESEARCH PERSONALITY



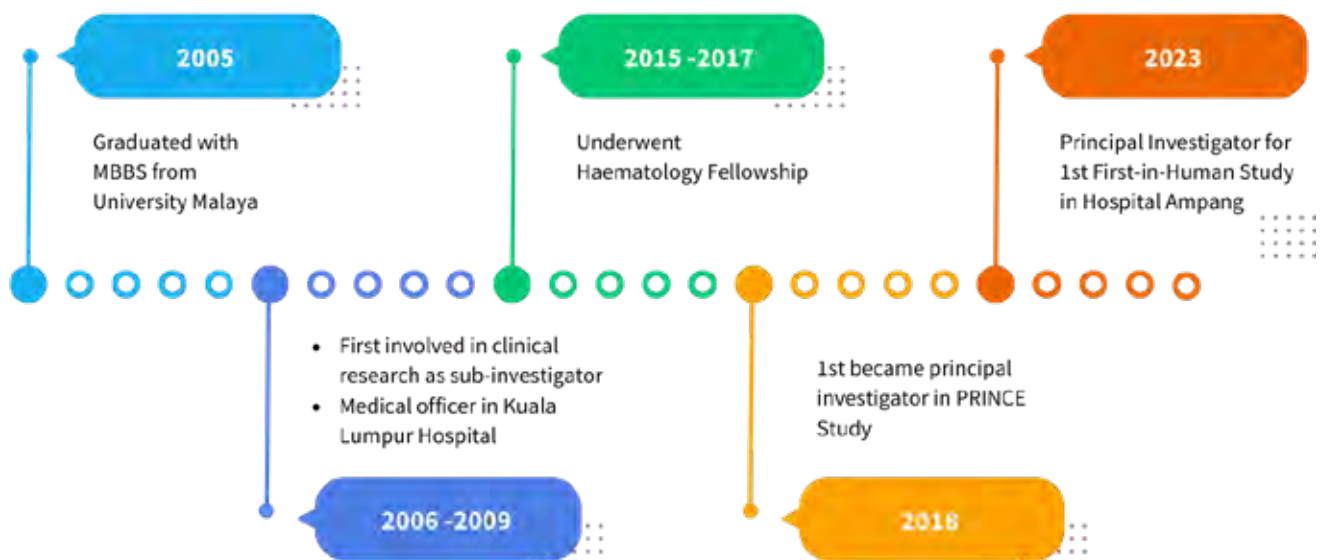
**Dr Veena Selvaratnam**

Consultant Haematologist, Ampang Hospital

## About Dr Veena Selvaratnam

I completed my haematology fellowship in Malaysia after earning my MBBS from University of Malaya. I am currently working as a consultant haematologist at Ampang Hospital, where I have a focus on maternal haematology, thrombosis, and hemostasis. In addition, I oversee Ampang Hospital's Clinical Haematology Reference Laboratory (MRKH). In addition to my employment at Ampang Hospital, I am a committee member of multiple local and internal congresses and hold multiple national and international professional positions.

### Roadmap to Investigator





### What is your personal vision as an investigator?

My main aim in participating in trials is so that patients can have an option for treatment. In some of these diseases, the treatment is non affordable and not sustainable; therefore there is some option for patients to obtain treatment. Also, as a clinician, I always hope for better treatment options for my patients, and what better way to offer these other than being involved in a clinical trial.

### Describe experience so far as early phase investigator which lead your readiness to take up First-in-Patient study?

My only other experience was a Phase 1b trial as a Sub I under Dr Jameela for a PNH trial. It went rather smoothly without much hiccups. A good CRC /CRM staff with vast experience is the key to being able to manage early phase trials. The team here have been doing trials since it was started many years back and have a sound understanding and grasp on how to conduct trials. The other drive for a Phase 1 trial was to help accreditate Ampang CTU for Phase 1 trial and therefore this was a good opportunity.

### Advice to budding investigators aiming to start their journey

Always keep an open mind and do things with honesty and and with best interests of patients in mind. With good intentions and goal in mind added with a sincere heart, hopefully things will go smoothly with God's grace. It is indeed extra work and time involved but its for a greater purpose; or at least that is the hope.



Dr Veena Selvaratnam in her office



Standing (L-R): Azra Raihanah Khairul Faizi, Wirdatulain Mohd Mastana, Wan Nor Atikah Che Wan Mohd Rozali, Dr Veena Selvaratnam, Nor Khazirah Zaini, Syatirah Abu Yazid & Nabillah Azirah Zakaria



# RISING STARS IN RESPIRATORY MEDICINE

Since 2012, Malaysia has demonstrated its ability to undertake trials encompassing a wide range of therapeutic disciplines, with over 2,300 sponsored trials completed and with a total of 23 protocols under pulmonary/respiratory therapeutic area involving 81 Ministry of Health trial sites. CRM would like to draw attention to the diligent effort of these Investigators in this issue. Let's hear about their experiences into this field.

## **Dr Chan Tha A Hing**

Physician & Pulmonologist

*Sultanah Bahiyah Hospital*



### **Areas of Interest in Research**

**Asthma, Chronic Obstructive Pulmonary Disease, Interstitial Lung Diseases (ILD), Lung Cancer**

I completed my medical degree from University Malaysia Sabah in 2010, following which, I pursued postgraduate exams and obtained MRCP (UK) in 2016. I have since completed my subspecialty training in Respiratory Medicine in 2022.

I was certified with Good Clinical Practice in 2017, which marked the beginning of my clinical research career. Since then, I have been involved as an investigator in various clinical studies including the ELEVATE study (idiopathic pulmonary fibrosis trial) and LITHOS study (asthma trial). I was also the advisor for a COVID-19 related study at Hospital University Kebangsaan Malaysia (HUKM).

I have published in both international and domestic journals, in addition to being a reviewer for the Medical Journal of Malaysia (MJM). Through research, I am committed towards advancing knowledge and treatment in respiratory medicine, and will be participating as an investigator in several upcoming asthma trials.

## **Dr Wan Jen Lye**

Head of Respiratory Unit &  
Pulmonologist

*Selayang Hospital*



### **Areas of Interest in Research**

**Severe Asthma, Interventional Pulmonology and Lung Cancer**

My medical journey commenced with an MBBS from International Medical University, followed by MRCP (UK) from the Royal College of Physicians, London (2016), Fellowship in Respiratory Medicine (Malaysia, 2022) & Fellowship of the Royal College of Physicians of Glasgow (2023).

As the Head of Respiratory for Klang Valley Cluster hospitals, I play a key role in setting up respiratory services of MOH hospitals situated within north & north-east region of Klang valley. In addition to serving as a visiting pulmonologist at Hospital UiTM Puncak Alam, I act as vice-treasurer of the Malaysian Association for Bronchology and Interventional Pulmonology, council member of the Malaysian Thoracic Society Council, and member of the Ministry of Health Malaysia's guideline committee for healthcare workers' TB management.

I have participated in conferences, abstract presentations, and publications addressing critical aspects of respiratory medicine. Currently, I am the principal investigator of AJAX study (asthma trial) and am also closely affiliated with medical associations, including being a British Medical Journal case report reviewer.

**Dr Tan Han Loong**  
Consultant Respiratory & Lung  
Transplant Physician

*Tuanku Ja'afar Hospital*



**Areas of Interest in Research**  
Chronic Obstructive Pulmonary Disease & Asthma

I obtained both my medical degree and internal medicine education (Doctor of Internal Medicine & MRCP) from UKM prior to pursuing my specialist training in respiratory medicine followed by fellowship in lung transplantation at Freeman Hospital.

I always believe that scientific research can help to enhance medical technological innovation, foster knowledge creation and aid disease control and have been involved in research since 2013. Even during my sub-specialist training, I was involved in four respiratory-related research, producing 3 manuscripts and having given five presentations as its outcomes. I also conducted the lung transplantation research collaboration between Malaysia and Freeman Hospital, in which the study findings were then presented during the European Respiratory Society International Congress 2023.

With the support of both HTJ's Head of Respiratory Unit Dr Raymund Dass and my colleague Dr Lee Xiang Ying, I am able to pursue my research journey, with now two ongoing studies focused on asthma and COPD respectively. My plans for the next few decades will be to work with all stakeholders to foster cutting-edge research while maintaining close attention to the everyday needs of patients.

**I always believe that scientific research can help to enhance medical technological innovation, foster knowledge creation and aid disease control**

**Dr Tan Han Loong**

**Dr Lee Chiou Perng**  
Respiratory & Internal Medicine  
Specialist

*Sultan Idris Shah Hospital*



**Areas of Interest in Research**  
Pulmonary Hypertension and Severe Asthma

I am currently practicing internal medicine and respiratory I underwent my sub-specialization in Malaysia and completed one year of advanced respiratory training in Melbourne, Australia, focused on the treatment of Pulmonary Arterial Hypertension and the use of biologics and immunotherapy for treating Severe Asthma. Upon returning, I pioneered the establishment of Pulmonary Hypertension and Severe Asthma Services at his institution.

I received training in interventional pulmonary medicine in Malaysia, where I presently conduct intricate interventional pulmonary treatments. These procedures include airway stenting, endobronchial ultrasonography (EBUS) for staging lung cancer, and basic flexible bronchoscopy. Moreover, I am certified by the European Respiratory Society as a Transthoracic Ultrasound provider.

In addition to my clinical practice, I have a strong interest in clinical research. I was previously appointed as Klang Hospital's Clinical Research Centre (CRC) deputy chief. As a principal investigator, I am now involved in multiple ongoing clinical trials and working hard to stay abreast of the most recent advancements in treatment alternatives. As a pulmonologist, I provide each patient with the most recent, customized care that is supported by strong evidence.

**Dr Lee's Research Snapshot (since 2016)**

Coordinating Principal Investigator	1 ISR Study
Principal Investigator	2 ISR Studies
Sub-Investigator	3 ISR Studies and 2 IIR Studies
Abstract Presentation	5 Presentations
Publications	4 Publications

# CRM TRIAL CONNECT 2024



Accelerating Malaysia in Global Clinical Trials

CRM TRIAL  
**CONNECT**  
9 - 10 MAY 2024

Connexion Conference & Event Centre, Kuala Lumpur

  
2024 SPONSORED  
RESEARCH AWARDS

**Clinical  
Trials Day**

in collaboration with

 **EORTC**  
European Organisation for Research  
and Treatment of Cancer  
*The future of cancer therapy*

 国立がん研究センター  
中央病院  
National Cancer Center Hospital

 **NCCR**  
National Conference  
for Clinical Research

Scan to register now!





# INFOGRAPHIC

## Recruitment Achievements in Global Sponsored Research 2023

### Top 3 & Top 5 Global Recruiter

#### Institute of Respiratory Medicine

Idiopathic Pulmonary Fibrosis  
Dr Syazatul Syakirin

#### Hospital Miri

Cardiovascular Diseases  
Dato' Dr. Fam Tem Lom

### Global 1st Recruiter

#### Hospital Tengku Ampuan Afzan

Non-Small Cell Lung Cancer  
Prof How Soon Hin

#### Hospital Umum Sarawak

Advanced Solid Tumors  
Dr Voon Pei Jye

#### Hospital Miri

Type 2 Diabetes  
Dato' Dr Fam Tem Lom

#### Hospital Sultanah Aminah

Generalized Pustular Psoriasis  
Dr Choon Siew Eng

#### Universiti Malaya Medical Centre

Non-Small Cell Lung Cancer  
Dr Tan Jiunn Liang

#### Hospital Queen Elizabeth II

Rotator Cuff Tendinopathy  
Dr Jeffrey Kee

### ASIA 1st Recruiter

#### Hospital Umum Sarawak

Non-Small Cell Lung Cancer  
Dr Voon Pei Jye

#### Hospital Sultanah Aminah

Warm Autoimmune Hemolytic Anemia  
Dr Azizan Bin Sharif

### SEA 1st Recruiter

#### Institute of Respiratory Medicine

Idiopathic Pulmonary Fibrosis  
Dr Syazatul Syakirin

#### Hospital Umum Sarawak

Atherosclerotic Cardiovascular Disease  
Dr Diana Foo

### APAC 1st Recruiter

#### Institute of Respiratory Medicine

Idiopathic Pulmonary Fibrosis  
Dr Syazatul Syakirin

#### Hospital Tengku Ampuan Afzan

Non-Small Cell Lung Cancer  
Prof How Soon Hin

#### Hospital Umum Sarawak

Advanced Solid Tumor (First In Human)  
Dr Voon Pei Jye

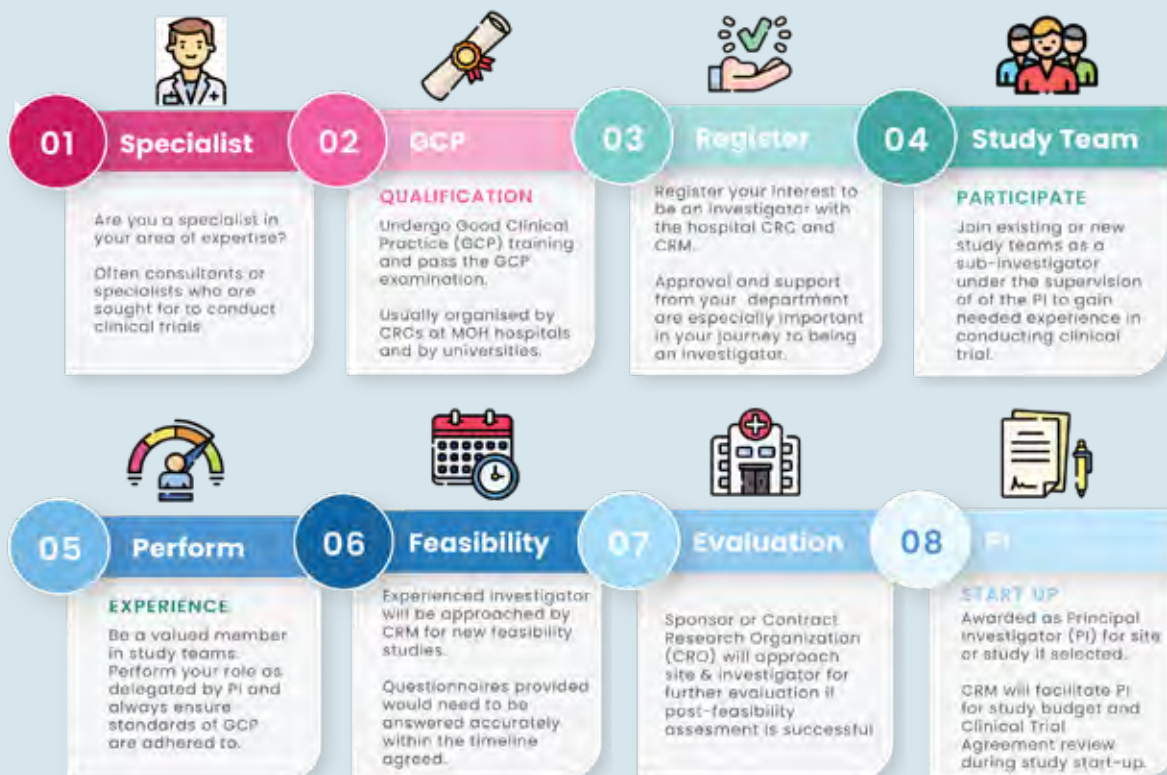
#### Hospital Pulau Pinang

Hidradenitis Suppurativa  
Dr Tan Wai Chiang

#### Hospital Tengku Ampuan Afzan

SLE with Lupus Nephritis  
Dr Fariz Sofhan

# 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





## **CRM CLINICAL TRIAL ADVERTISEMENT SERVICES**

### **Platform**

- Facebook & Instagram
- Targeted audience approached via Sponsored Ads

**contact: [brcc@clinicalresearch.my](mailto:brcc@clinicalresearch.my)**



## **CRM STUDY MATERIAL DESTRUCTION SERVICES**

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

**contact: [komala@clinicalresearch.my](mailto:komala@clinicalresearch.my)**





# FEATURED SITE

## INSTITUT KANSER NEGARA (NATIONAL CANCER INSTITUTE)



Institut Kanser Negara (NCI) was established to address the needs of growing issues related to cancer in the country by providing specialized facilities and medical treatment for adult cancer patients. Beginning its operations since 2 September 2013, this hospital was equipped with advanced equipments and latest technologies to cater various aspects of diagnosis and therapeutics of cancer diseases as NCI provide specialist clinics, inpatient, daycare and clinical support services.

Besides providing routine patient care services, as an institution NCI also strives to become a centre of excellence in cancer treatment through active engagement in research and education, which aim to improve patient's care in various disciplines through evidence based medicine.

### MAIN CLINICAL SERVICES

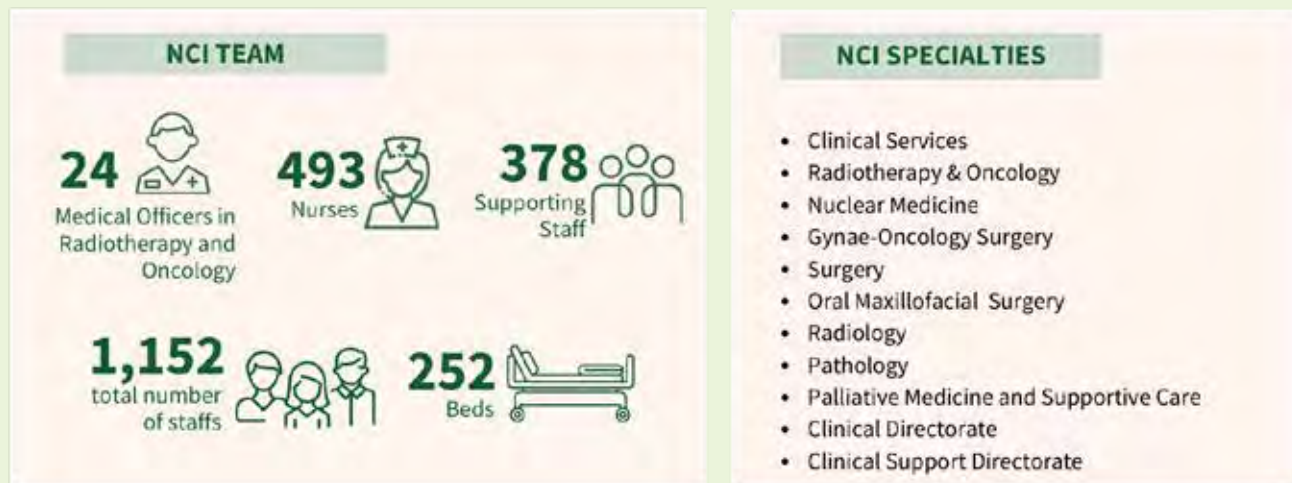
- Radiotherapy & Oncology
- Anesthesiology and Intensive Care
- Nuclear Medicine
- Pathology
- Oncology Surgery
- Acute Cancer Care
- Gynae-Oncology
- Palliative Medicine and Supportive Care
- Oral & Maxillofacial Surgery
- Traditional and Complementary Medicine



### NCI FACILITIES

- Oncology Clinic
- Radiology Equipment
- Radiotherapy Equipment
- Nuclear Medicine Equipment
- Emergency Department
- Molecular Laboratory
- Centralised Blood Taking Area
- Multidisciplinary Clinic
- Outpatient Pharmacy
- Cytotoxic Drug Reconstitution





## CLINICAL RESEARCH CENTRE AT NCI

Clinical Research Centre (CRC) in NCI was officially established in 30th October 2014 with the purpose of coordinating research activities for both Investigator Initiated Research (IIR) and Industry Sponsored Research (ISR) conducted within NCI, as well as providing research related consultation and trainings for MOH staff. In 2016, NCI was awarded with its first ISR and since then the number of IIR and ISR conducted in NCI keep increasing each year which reflects a tremendous interest in research by NCI investigators and study team as well as from the industry.

In 2018, NCI was awarded Clinical Trial Site of the Year, and the Head of CRC NCI, Dr Wong Yoke Fui (Clinical Oncologist), was awarded Top Recruiter, during the 2nd NCI Research Day and Clinical Trials Day. NCI continues to gear up its position after being after being selected under Phase I Realization Program 2.0 in 2022, which will focus towards establishment of NCI as an accredited Phase I Clinical Trial Site in Malaysia. In July 2023, NCI has been selected by Medpace as the First Flagship Site in Asia Pacific Region, which will open more opportunity for collaborative research of interests.



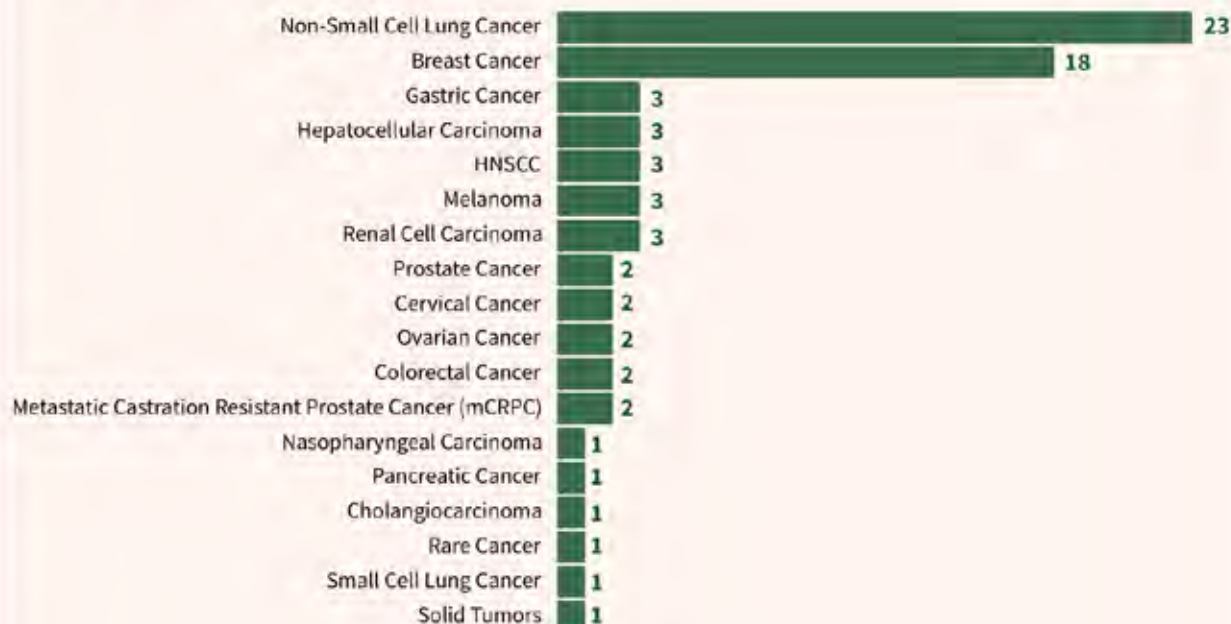
### SNAPSHOT OF SPONSORED CLINICAL RESEARCH ACTIVITIES IN NCI (2016 - 2023)

Awarded	72
On-going	27
Start-up	24
Closed/Completed	12
Dropped	9

### ACCOMPLISHMENTS IN CLINICAL RESEARCH

Year	Accomplishment
2018	Sponsored Research Awards - Clinical Trial Site of the Year
2018	Sponsored Research Awards - Top Recruiter
2023	First Patient Randomized in Malaysia for EVOKE Study (NSCLC)
2023	First Patient Randomized in Malaysia for INAVO Study (Breast Ca)
2023	Medpace Flagship Site Program

### ISR BY THERAPEUTIC AREAS





# MEET OUR TEAM

## Sarena Hasniza Shamshuddin

*Finance Manager (Accounts Receivable)  
5-time CRM CEO Award Recipient*



### About My Role

I started my journey in CRM since mid-2013, beginning from an executive to now a managerial role. As a Finance Manager (Accounts Receivable) at CRM, my primary responsibility is managing the entire accounts receivable department. I also keep an eye on the submission of payment trackers requested by CRM study coordinators at sites to sponsors and CRO, ensuring that invoices are released on time in accordance with Standard Operating Procedures (SOP), which I review and confirm. It is customary to follow up on unpaid invoices that are more than sixty days past due.

Monthly practices require submission of various reports, including debtor ageing, CTA value, CRM management fees, internal reconciliation, and SST submission for Royal Malaysian Customs Department. In addition to my regular work as a finance manager, I also work for CRM as an internal auditor and am a member of the Code of Conduct (COC) Committee.

To ensure timely payment, it's crucial to send reminders and invoices to sponsors and CROs, ensuring adequate funding for clinical research. The invoice should also include CRM Management Fees, which are vital for the company's efficiency and one of CRM's primary revenue streams.

The Finance team creates an Excel sheet payment tracker using the Clinical Trial Agreement Budget, which is accessed by the Main Study Coordinator via OneDrive. The tracker is updated quarterly or monthly, and then sent to the Sponsor/CRO for approval. The Sponsor/CRO can either provide an internal document for invoice creation or request CRM Finance to issue the invoice directly.

The Associate Regional Manager receives a quarterly copy of the Master Payment Tracker, enabling them to consult with their Main Study Coordinator about billing issues and evaluate the latest billing period for each treatment. If discrepancies are found, the Main Study Coordinator is requested to provide the Tracker for resolution. The Finance and Operations teams collaborate to ensure bills are generated up to the latest billing period.

### A career as an Accounts Receivable Manager in the clinical trial industry offers several prospects and opportunities, which include:

#### Industry-Specific Expertise

Working in the clinical trial sector provides you with specialized knowledge of the industry's unique financial processes, regulations, and challenges.

#### Compliance and Regulatory Knowledge

Clinical trials often involve compliance with various regulatory standards. As an Accounts Receivable Manager, you would gain expertise in navigating these regulations, ensuring financial processes align with industry and regulatory requirements.

#### Understanding of Research Funding

Clinical trials are funded through various sources, including pharmaceutical companies, government grants, and private investors. Managing accounts receivable in this context involves understanding the diverse funding mechanisms and ensuring proper invoicing and reimbursement processes.

#### Collaboration with Research Teams

You may work closely with research teams, investigators, and other stakeholders in the clinical trial process. This collaboration can provide a unique perspective on the financial aspects of research projects.

#### Billing for Clinical Services

Clinical trials often involve billing for various services, including patient visits, laboratory tests, and other trial-related activities. Managing accounts receivable in this setting requires a keen understanding of the billing processes specific to clinical trials.

#### What's Next?

The CRM Finance team is eager to carry out its future ambitions, which include digitising the payment tracker into a system, in order to keep up with the rapid advancements of the modern world and to ensure efficiency in the payment process. The project is projected to be completed in June 2024.

## Engku Fatimah Syairah Binti Engku Safruddin

*Senior Study Coordinator  
CRM CEO Award Recipient 2023*



### What inspired you to be part of the clinical research industry?

I was inspired when I was in USM back in 2016. I was a backup SC there for 2 oncology studies and was able to be involved in a few of the patient visits, blood sampling, and IP preparation process. It was a lot to take in because that was my first experience, but I find it quite interesting even though the patient visits can drag on from morning until evening as the satisfaction from being able to help trial participants get alternative treatment for cancer is very rewarding. The feeling is indescribable as patients were also very cooperative and their conditions improved after taking the IP. From there I knew this is something I want to explore on.

The complexity of the protocol for each research. Different research has a different way on how to execute the protocol correctly. There is always something more to learn. New research comes whereby new procedures or different flow/design will be implemented, hence different kind of challenges to be faced. With experience over time, there is something about that driven adrenaline rush with the desire to execute the clinical research in a better way and utmost efficiency. Once you learn to adapt to various complexity of the research, you will eventually know how to tackle the hardship that comes with it.

### How do you keep up to date with clinical trial best practices?

Trying to be involved in studies of multiple therapeutic area even though in some of these, I am only involved as backup SC for other studies, much can be gained by just observing my colleagues in their studies. Good rapport with sponsors and CRO also helps a lot in this case as they are assigned to monitor your practice at site. Thus, always ask for any advice or tips from them because there is always room for improvement.

### What has been your greatest learning opportunity in clinical research?

Audits. I was able to work with various auditors from sponsors. You're already in it, so dive deep. Do not let it pass by and never treat it as one-time thing only, think about how lucky you are to experience it because it makes you stronger and gives you more insight on how clinical research should be. It can be mentally exhausting but at the end of the day, treat it as one of the stepping stone for your career progression. For any mistakes or findings discovered, do not blame others, or lash out but think hard on why it happened and how you should improve and resolve the matter.

### What helps you support your role?

Staying resilient and flexible. Do not say no or be reluctant to anything you don't know how to do or have less experience with. Be flexible and seek opinions and guidance from others because this is something that you can explore more. It may or may not be a valuable experience for you, but it will teach you something or give you more insight on how things are done. Knowledge is key to success. Stay resilient and do not dwell on past errors as clinical research is a fast-paced industry. Hence be optimistic and stay positive throughout the way.

### What drives you to move forward?

What drives the momentum is more on challenging myself to become better each day as clinical research can be tough and exhausting at times. I just keep telling myself that if i can get this far, why can't I do more. Failure is not a stopping point, its where success is born. Whether we like or not, choices that we make on daily basis can sometimes lead to failure. It's just a matter of whether you choose to deal with it or run away from it. Avoid the latter, act, and keep improving.



Receiving CRM CEO Award 2023 for outstanding performance from CEO Dr Akhmal Yusof

# CRM IN PHOTOS



Meeting with Chyromed

12  
Jul



Second Board of Directors Meeting

26  
Jul



Meeting with the team of Siriraj Hospital, Mahidol University Thailand

28  
Jul



Meeting with IRDI, IMU

3  
Aug



Meeting with GSK team

8  
Aug



Meeting with The College of American Pathologists

9  
Aug



Meeting with Syneos Health

16  
Aug



Visit by ICR Director Datin Dr Sheamini Sivasampu

16  
Aug



Meeting with Policy and International Relations Division

22  
Aug



Meeting with Quat Research

28  
Aug



Meeting with brandME

30  
Aug



Meeting with Flat World

26  
Sep



# CRM IN PHOTOS



Meeting with AstraZeneca

27  
Sep



Meeting with PPD

13  
Oct



Meeting with Novartis

13  
Oct



Meeting with China Assoc. for  
Vaccines, Suzhou Advaccine  
Biotechnology Co Ltd & MVAC  
Biotech Sdn Bhd

17  
Oct



Meeting with Zhiwei Herb  
and Nextcomm Group

1  
Nov



Commemorating KPI 2023  
achievement

7  
Nov



Meeting with Gilead team

8  
Nov



Meeting with Remedy Corp

15  
Nov



Meeting with Novo Nordisk

21  
Nov



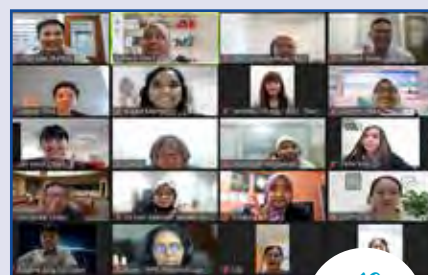
Meeting with MAKNA

22  
Nov



Meeting with Malaysian  
Genomics Resources Centre  
(MGRC)

27  
Nov



Preparation for Regulatory  
Inspection Workshop

12  
Dec

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