


BY CLINICAL RESEARCH MALAYSIA

CRM Bulletin

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**PEAKING PRESTIGE:
MALAYSIA'S LEADING
CLINICAL RESEARCH
MILESTONES**

**RISING STARS IN
NEPHROLOGY**

FEATURED SITE
Institut Perubatan
Respiratori (IPR)

**RESEARCH
PERSONALITY**

Dr Syazatul Syakirin



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



Warmest welcome to CRM Bulletin 28!

As the midpoint of 2024 is passing by, it's remarkable to reflect on the significant achievements and impactful events that have shaped these past few months. The pace of progress has been swift, but the results speak volumes.

In this edition, we're excited to highlight of our recent milestones, introduce to the dedicated team driving our mission, and review our recruitment successes for the year. We proudly mark the return of CRM Trial Connect, our annual international conference, which included two insightful workshops held in collaboration with the European Organization for Research & Treatment of Cancer (EORTC), the National Cancer Center Japan (NCC), and the NPRA. This event was a key opportunity for us to strengthen existing partnerships and forge new ones.

We are particularly thrilled to announce that Malaysia ranks among the Top 30 countries globally and 1st in Southeast Asia for country readiness in global clinical trials according to IQVIA report on "Rethinking Clinical Trial Country Prioritisation." This milestone reflects our growing excellence and readiness in clinical research. We're also honoured to have received the prestigious UK-Malaysia Partnership of the Year Award, recognising our commitment to clinical trials and governance.

This bulletin also features the inspiring journey of one of our principal investigators and a deep dive into one of our sites. Here's to a continued journey of innovation and success in the rest of 2024!

Our commitment to Humanity, Stability, and Sustainability remains at the core of our operations. We remain committed to delivering clinical trials with Speed, Reliability, and Quality, driven by our operational excellence and robust partnerships

Thank you to our partners, stakeholders, and the entire CRM team for your unwavering support. Together, we will continue to advance healthcare and research in Malaysia and beyond.

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



PMCC's Mission of Excellence: A Collaborative Partnership with CRM

6 May 2024 – CRM's collaborative partnership with the Princess Margaret Cancer Centre (PMCC) led to PMCC's Mission of Excellence to Malaysia. The team visited FIH site, Sarawak General Hospital and connected with the team there in the early part of their visit.



Best Practices in Phase I Studies: Insights from Princess Margaret Cancer Centre

8 May 2024 – Ms. Gagan Sran, Ms. Lindsay Carlsson, and Ms. Carey Yang from Princess Margaret Cancer Centre (PMCC) led an insightful session with CRM Study Coordinators. They shared best practices for managing Phase I studies through case studies and group discussions, highlighting the importance of proactive planning and effective communication within the study team.



Mastering Project Management for Clinical Trials

8 May 2024 – A large group of experienced SCs attended the 'Project Management in Clinical Trials' training led by Ms. Adeline Yeoh from Syneos Health. The session covered how project management concepts and tools can be effectively applied to coordinate clinical trial activities at the site.



IC3D 2024 Conference

13-14 May 2024 – CRM attended the International Conference on Drug Discovery and Development (IC3D) 2024, along with Dr. Voon Pei Jye as one of the speakers presented on enhancing outcomes with early phase oncology trials and valuable insights into innovative methodologies and strategies for advancing cancer treatment and improving patient outcomes.



CRM at DIA China 2024

20 May 2024 – CRM and NPRA marked their presence at the recent DIA China 2024, sharing Malaysia's value proposition for clinical trials and the regulatory landscape of the country.



3rd I Am Aware Roadshow of 2024

21 May 2024 – In honor of Clinical Trials Awareness Month, CRM held its third I Am Aware Roadshow of 2024 at Miri Hospital. The event aimed to educate the public about the benefits of participating in clinical trials.



Forging New Opportunities with Novartis

29 May 2024 – Datuk Seri Dr. Dzulkefly bin Ahmad, the Minister of Health Malaysia, Datuk Dr. Muhammad Radzi Bin Hassan, DG of Health and CRM CEO met with Dr. Lutz Hegemann, President of Global Health & Sustainability at Novartis, and his team from Basel. The Novartis team praised Malaysia's excellent clinical trial delivery and expressed their commitment to investing in new opportunities. They also look forward to Malaysia's role as ASEAN Chair in 2025 and its leadership in regional health initiatives, including clinical research.



Virtual Protocol Compliance Workshop 2024

29 May 2024 – CRM successfully conducted its Virtual Protocol Compliance Workshop 2024. CRM extend our thanks to the speakers for their invaluable insights, which will greatly benefit attendees in their clinical tasks.



Patient Recruitment & Retention Workshop 2024

29 May 2024 – CRM has successfully conducted the 2nd series of its Patient Recruitment & Retention workshop for 2024, attended by 36 internal and external stakeholders. The workshop offered valuable strategies and insights to enhance patient engagement and improve recruitment outcomes.



Strengthening Global Clinical Trial Partnerships in Basel

31 May 2024 - It was a series of productive meetings in Basel, where the Minister of Health Malaysia and CRM CEO engaged with several biopharmaceutical organizations, including Novartis, Roche, BeiGene, and Swissrocket. The focus was on positioning Malaysia as a key site for multi-regional clinical trials, leveraging its mature ecosystem and excellence in trial delivery. The discussions strengthened both old and new connections, setting the stage for Malaysia to enhance its global footprint in clinical trials.



Kuala Lumpur Hospital Research Day

6 June 2024 - CRM participated in the 7th HKL Research Day at Kuala Lumpur Hospital (HKL) with CRM CEO Dr. Akhmal Yusof. The event highlighted the growth, challenges, and future direction of clinical research in Malaysia. A sincere gratitude to Dr. Syazatul Syakirin Sirol Aflah from the Institute of Respiratory Medicine for sharing her insights during the CRM session talk.



Malaysia Tops Southeast Asia in Industry-Sponsored Studies

11 June 2024 - A landmark day as Malaysia leads Southeast Asia in industry-sponsored studies for 2023-2024 (to date)! Truly grateful for the dedicated efforts of CRM's clinical research team across public hospitals, university hospitals, and private centers. Kudos to everyone who has supported and enabled this ecosystem, including our regulators, EC members, industry partners, sponsors, and CROs. Great work truly yields fantastic results!



DIA 2024 Global Annual Meeting in San Diego

18 June 2024 - CRM's team including the Head of Clinical Operations, and the Evaluation and Safety of Investigational Product Section, NPRA, attended DIA2024 in San Diego. The conference explored topics such as the future of regenerative therapies and the role of public-private partnerships in advancing healthcare.



1st Batch of CRM Centre of Excellence Graduates

21 June 2024 - CRM Centre of Excellence concluded its 1st batch of the Foundation Program for Study Coordinators, following 12 weeks of theoretical training and site attachment. Kudos to the trainees for completing the program and embarking on their journey in clinical trials. CRM wished them all the best!



4th I Am Aware Roadshow of 2024

25 - 26 June 2024 - CRM successfully conducted its 4th I Am Aware Roadshow of 2024 at Sultan Abdul Halim Hospital, in conjunction with World Blood Donor Day. The event highlighted the benefits of participating in clinical trials, aiming to raise public awareness about their importance.



Nurturing New Talents (NNT) in Sponsored Research 2024

26 June 2024 - CRM successfully organised NNT in Sponsored Research at Sultan Abdul Halim Hospital. Thanks to the speakers, Dr. Arvindran Alaga (Head of Respiratory Medicine Department, Hospital Sultanah Bahiyah) and Dr. Balraj Sethi (Country Medical Affairs Head, Novartis) for their valuable insights.



Advancing Clinical Research in Southeast Asia

2 July 2024 – CRM attended a 2-day policy workshop organized by the Academy of Medical Sciences (UK) and the Academy of Sciences of Malaysia, focusing on advancing diagnostics and therapeutics in Southeast Asia. CRM shared insights on Malaysia's clinical trial capacity building, and Dr. Voon Pei Jye discussed the nation's early phase clinical research development.



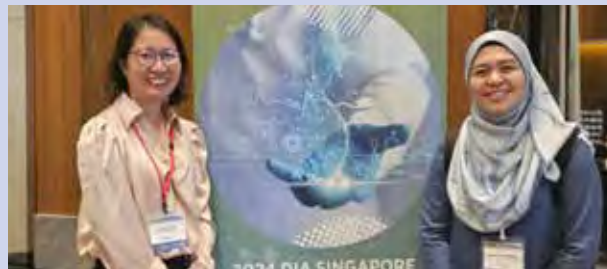
CRM at 18th ASEAN SOMHD: Advancing Clinical Trials

2 July 2024 – CRM represented Malaysia at the 18th ASEAN Senior Officials' Meeting on Health Development (SOMHD), presenting a new initiative to advance the region's prosperity through industry-sponsored clinical trials.



CRM x NCSM collaboration

15 & 29 July 2024 – CRM and the National Cancer Society Malaysia successfully conducted an insightful live session on Facebook and YouTube. It was an honour to hear from Dr. Mastura, Consultant Clinical Oncologist & Radiotherapist, Dr. Ezal, Clinical Oncologist and Mr. Safri, a clinical trial participant, who shared their valuable stories.



DIA Singapore Annual Meeting

16 - 17 July 2024 – CRM participated in the DIA Singapore Annual Meeting 2024, joining regulators, patient representatives, and industry leaders to foster collaboration in clinical research and regulation. The event offered valuable insights into drug development and innovation, highlighting the crucial role of patients, and provided impactful learning and networking opportunities.



Good Clinical Practice (GCP) Refresher Workshop

17 July 2024 – CRM successfully conducted its 2nd series of GCP Refresher Workshop of 2024 at Shah Alam Hospital. The workshop aimed to enhance the knowledge and skills of attendees in Good Clinical Practice. Special thanks to Ms. Yoong Kai Shen for her time as the speaker. We hope the workshop provides valuable benefits to all participants!



Singapore Clinical Research Institute (SCRI) Trials Symposium 2024

30 & 31 July 2024 – CRM attended SCRI Clinical Trials Symposium 2024, reconnecting with familiar faces and forging new relationships. CRM CEO, Dr Akhmal Yusof was one of the speakers & panelist, sharing insights on the latest updates in Malaysian clinical trials during the 'Trends in Clinical Trials' session.

SPOTLIGHT FEATURE

CRM Trial Connect 2024



Kuala Lumpur, 9 May 2024 - Clinical Research Malaysia (CRM) successfully held its third annual conference, CRM Trial Connect 2024. This event was preceded by two key workshops: "Biostatistics in Oncology Research" and the Regulatory Workshop. These workshops were conducted in collaboration with the European Organization for Research & Treatment of Cancer (EORTC), the National Cancer Center Japan (NCC), and the NPRA.

This year's conference was held in collaboration with the European Organization for Research & Treatment of Cancer (EORTC) and the National Cancer Center Japan. This 2-day event aimed to spotlight Malaysia's achievements in sponsored clinical research and foster collaborations between local and international stakeholders. Nearly 1,000 attendees from over 130 organisations, including the biopharmaceutical and medical device industries, contract research organisations, academic institutions, and the healthcare sector, participated in the event.

The conference was officiated by the Minister of Health, YB Datuk Seri Dr Haji Dzulkefly Ahmad, on behalf of the Malaysian Prime Minister, at the Nexus Connexion Conference & Event Centre in Kuala Lumpur. Emphasising Malaysia's standing as one of the top countries for sponsored clinical research in South-East Asia, the Minister of Health expressed his aspirations to attract a higher market share of global sponsored trials to the region, highlighting the nation's supportive research landscape and diverse population.

Throughout the event, various engaging forums took place. Esteemed speakers from the public, university, and private sectors shared their insights into the emerging industry of clinical trials in Malaysia. A patient engagement forum provided a platform for clinical trial participants to share their journeys, while a discussion on accelerating clinical trial market growth in ASEAN was moderated by Khairiy Jamaluddin, featuring contributions panellists from ASEAN countries.

National-level discussions covered topics such as translating clinical practice into research, a Malaysian study on drug-coated balloons, and innovative approaches to trial emulation and data-linkage for vaccine effectiveness in Malaysia. One of the conference highlights was the global network of excellence session, chaired by Dr Kenichi Nakamura from the National Cancer Center Japan (NCC). This session featured speakers from the NCC, ATLAS, and EORTC, who shared overviews and experiences of international clinical trials. Additional sessions also covered regulatory and ethics tracks, early-phase clinical trial excellence, clinical research support services, and clinical trial innovation.

The conference concluded on a high note, with CRM praised for orchestrating yet another successful international event. The closing keynote address by Datuk Dr Muhammad Radzi Abu Hassan, the Director General of Health Malaysia, summarised the key takeaways from the two-day event, leaving attendees inspired and excited for the future of clinical research in Malaysia.

Sponsored Research Awards 2024

Kuala Lumpur, 9 May 2024 - The CRM Trial Connect Conference 2024 also acknowledged clinical research stakeholders, in conjunction with the International Clinical Trials Day celebration. During the event, Datuk Seri Dr Haji Dzulkefly Ahmad presented the CRM Clinical Research Leadership Award to Datuk Amar Prof Dr Sim Kui Hian, the Deputy Premier and Minister for Public Health, Housing and Local Government of Sarawak for his exemplary role as a pioneer in the development of clinical research in Sarawak and Malaysia. The CRM Sponsored Research Awards were also presented during the conference to the top investigator, trial sites and industry members, for having achieved significant accomplishments in 2023.



CRM CEO Awards 2023

CRM is committed to recognising and rewarding its employees who exemplify the principles of humanity, stability, and sustainability through the Chief Executive Officer (CEO) Awards program. This annual program celebrates employees who have demonstrated exceptional dedication and contribution to the company's mission and values.

Congratulations to all our 2023 CEO Award recipients! Your commitment to excellence and embodying CRM's core principles has not only strengthened our team but also contributed significantly to our continued growth and success.

Individual Category

FTE Project - Ease of Workload Assesment



Alvin Bundoi

First in Human Super Rookies / Site - Sarawak General Hospital



Erfan Salbi, Fong Yian Ching, Irene Bragai Segaran & Lim Li Fang

Team Category

Global Fee - Ver! / Site - Tengku Ampuan Afzan Hospital



Adibah Hamiza, Fatma Diyana, 'Izzah Atira, Nur Liyana, Murniyati, Noor Sami'ah, Nor Naimah, Nur Ezzati Fatin, Nur Faqihah, Suriani Yaacob, Syafiqah Hanani & Zati Nabilah

CRM Won the Business Excellence Award 2024 for UK-Malaysia Partnership of the Year!



Kuala Lumpur, 23 May 2024 - AstraZeneca and Clinical Research Malaysia won the prestigious UK-Malaysia Partnership of the Year Award, recognizing their collaboration in clinical trials, governance meetings, and site visits. This prestigious award ceremony was hosted by the British Malaysian Chamber of Commerce (BMCC) and representing CRM in accepting the award was Ms Zaleha Yusof, CRM's Head of Human Resources.

This award is a testament to the fruitful working partnership between CRM & AstraZeneca, which saw a significant increase in clinical trials in 2023 as well as the expansion of its clinical research team in Malaysia. A heartfelt gratitude to CRM team for the hard work & contribution, which have been instrumental in achieving this successful partnership.

Assessed by a panel comprising 8 representatives from the University of Nottingham Malaysia, 6 representatives from the University of Nottingham UK, spanning China and Malaysia, and 5 representatives from the British Council, this award underscores the significant synergies fostered through collaborative joint ventures.



Malaysia Ranks 1st In Southeast Asia For Country Readiness In Global Clinical Trials



Kuala Lumpur, 26 July 2024 - Malaysia is among the Top 30 in the world and leading in Southeast Asia in terms of country readiness for global clinical trials, according to the IQVIA report on "Rethinking Clinical Trial Country Prioritisation."

The report, which was published in July 2024, had mapped global clinical trial opportunities based on 17 key metrics, including healthcare accessibility, clinical trial efficiency, regulatory capabilities, and investment opportunities. Malaysia is recognised among the Top 25 countries for three out of the four clinical trial types indicated, with Indonesia as the only other Southeast Asian country listed under one of the trial categories.

The report highlights Malaysia's strong performance in patient availability and operational readiness, positioning it optimally for global clinical trials. Since 2023, Malaysia has led the region in trials, particularly in oncology, infectious diseases, and cardiology. With over 2,450 clinical trials conducted since 2012, the industry has contributed RM 1.38 billion to Malaysia's Gross National Income. This growth has attracted major pharmaceutical and contract research organisations to expand in Malaysia, increasing the demand for clinical research talent.

In response to this demand, Clinical Research Malaysia (CRM) established the CRM Centre of Excellence (CoE), officiated by the Minister of Health and Chairman of CRM, YB Datuk Dr Dzulkefly Ahmad. This program is aimed at developing local talents and providing them a foundation to kickstart their career in clinical research. The CoE also propels CRM's Mission 2033 to develop clinical research professionals in the country by creating 4,000 skilled jobs in clinical research.



Malaysia Chosen by International Organisations As Clinical Trial Hub In The Region



Kuala Lumpur, 9 May 2024 - At the CRM Trial Connect 2024 officiation ceremony, CRM announced a new partnership with Novo Nordisk (NN) and recognised its ongoing collaboration with AstraZeneca (AZ) in the presence of Minister of Health Datuk Seri Dr Haji Dzulkefly Ahmad. These partnerships highlight Malaysia's growing role as a global clinical trial hub.

Novo Nordisk, a leading global healthcare company, aims to enhance its strategic trial sites in Malaysia through this collaboration with CRM. The partnership will boost Malaysia's clinical research landscape. Serdar Kizilcik, Vice-President and General Manager of Novo Nordisk Malaysia, emphasized the company's commitment to expanding clinical trials in Malaysia across various therapeutic areas.

Since CRM's partnership with Sarawak General Hospital (SGH) in early 2023, AstraZeneca has significantly increased its research presence in Malaysia, expanding its clinical research workforce by 50% compared to 2022. AstraZeneca has also awarded a First-in-Human (FIH) study to Sarawak General Hospital, led by Dr. Voon Pei Jye, marking Malaysia's first FIH trial using a biological product.

Additionally, other organisations such as PAREXEL Malaysia and BeiGene, have established their presence in Malaysia, with PAREXEL setting up a Data Management Centre and BeiGene expanding its R&D and workforce in the country.

Partnership Forged with Singapore Research Organisations



Singapore, 30 July 2024 - The Memorandum of Understanding entered today is aimed to explore potential areas for collaborations in clinical research, that is achieved through understanding of healthcare and research landscape in Singapore and Malaysia.

Through this partnership, all 3 organisations will drive initiatives towards promoting and enabling knowledge exchange, innovation and training to improve the quality of research.

This partnership also enables both SCRI & CADENCE to tap into Malaysia's clinical research networks through CRM's outreach. With both Malaysia & Singapore leading in clinical research capabilities within Southeast Asia, this collaboration serves as a precursor towards future joint clinical research initiatives between both nations.

RESEARCH PERSONALITY



Dr Syazatul Syakirin

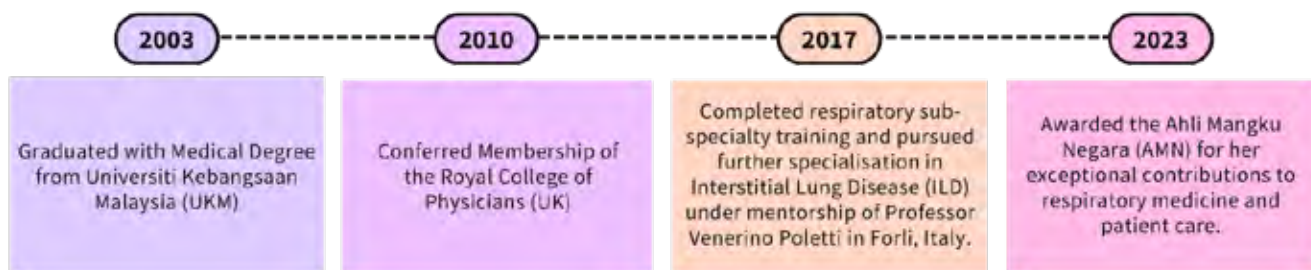
Respiratory Consultant at
Institut Perubatan
Respiratori at Kuala Lumpur

About Dr Syazatul Syakirin

Dr Syazatul Syakirin serves as a respiratory consultant at the Institut Perubatan Respiratori (IPR) in Kuala Lumpur. She is a distinguished expert in ILD (Interstitial Lung Disease) and leads the Malaysia Thoracic Society's (MTS) Special Interest Group in Interstitial Lung Disease (MTS-SIG-ILD), fostering knowledge and collaboration in this niche. Her unwavering dedication and pursuit of excellence have established her as a respected figure in respiratory medicine.

She moderates the monthly ILD multidisciplinary conference with the thoracic radiology group and serves as the Course Advisor and Director for the annual national ILD course. Additionally, she participates in various MTS initiatives, including spirometry training and the scientific committee of the annual MTS congress. She spearheads numerous industry-sponsored research studies on fibrosing ILD and is globally recognised as a top recruiter in the Idiopathic Pulmonary Fibrosis study. She also co-authored a chapter on ILD treatment with renowned expert Prof. Azuma Arata. Her contributions extend internationally through participation in conferences and research endeavours.

Dr Syazatul Syakirin's Roadmap to Investigator



Clinical Research Experience

SUB-
INVESTIGATOR
IN

18 STUDIES

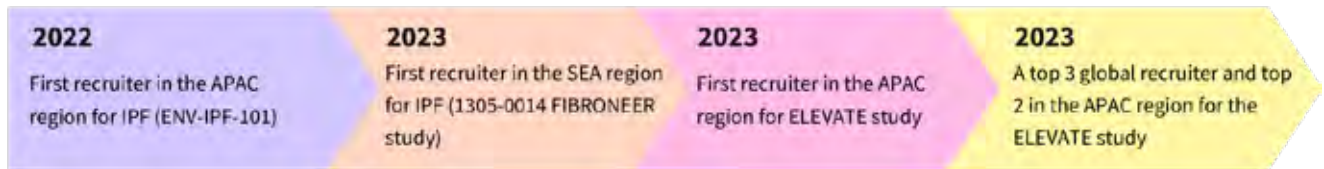
PRINCIPAL
INVESTIGATOR
IN

14 STUDIES

Current Areas of Interest in Research

Respiratory medicine, particularly in rare clinical entity like Interstitial Lung Disease (ILD)

Recruitment Achievements



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

My journey into clinical research began during my second year of respiratory training as a sub-investigator in an asthma study. This sparked my interest and ambition to lead clinical trials. I diligently gained the necessary skills and began my journey as a principal investigator with a trial on bronchiectasis. This pivotal moment transitioned my aspirations into reality.

I then had opportunities to research interstitial lung disease (ILD), a field I am passionate about despite its complexity and challenges. One major challenge was finding patients who met strict study criteria, which required close collaboration with healthcare providers and thorough screening. Convincing patients to participate was another hurdle, needing clear communication about the study's purpose, risks, benefits, and their role. Building and maintaining trust through consistent and respectful communication was crucial to keeping patients engaged and adhering to the protocol. These experiences emphasized the importance of perseverance, strategic planning, and effective communication in clinical research.

What motivates you to conduct clinical trials?

What motivates me is the opportunity to contribute to cutting-edge therapies that can revolutionize medical practices and benefit patients worldwide. The prospect of addressing unmet medical needs, enhancing treatment efficacy, and improving patient outcomes drives my commitment to clinical research.

Tell us an unforgettable accomplishment as an investigator?

An unforgettable accomplishment would be the highlight of my achievements in clinical trials includes being the first recruiter in the APAC region for IPF (ENV-IPF-101) in 2022, and again for the ELEVATE study in 2023. In 2023, I also became the first recruiter in the SEA region for IPF (1305-0014 FIBRONEER study). Additionally, I was recognised as a top 3 global recruiter and top 2 in the APAC region for the ELEVATE study.

What is your personal vision as an investigator?

My personal vision is to contribute meaningfully to clinical trials by conducting research that enhances understanding and treatment options for patients, especially in respiratory diseases. I aim to support advancements in medical knowledge and practice, collaborating closely with healthcare professionals to improve patient outcomes and contribute to healthcare innovation.

Could you offer some advice for those who are looking to begin a career in clinical research?

The importance of curiosity, persistence, and a commitment to learning need to be emphasised. It is essential to approach research with an open mind and a passion for making a difference in patient care. Stay updated with the current literature and developments in own medical field, it will help to develop strong analytical and critical thinking skills.



Standing (L-R): Normaniza Muhammad, Tommy Reynolds bin Thomas, Mardhiyah Abdul Razak, Nik Nurdiana Nik Izhar, Sharifah Alia Amilla Syed Hamid, Farhana Hassan & Kamani A/P Vijayan Seated (L-R): Dr Diyana Sabri, Dr Noraishah Sulaiman, Dr Norni Natriah Mohamad Yusoff, Dr Syazatul Syakirin Sirol Allah, Dr Zamzurina Abu Bakar, Dr Normaszuhailla Ab Hamid & Zulsairi Bin Mohd Pauzi



Dr Syazatul Syakirin at her office

RISING STARS IN NEPHROLOGY

Since 2012, nephrology studies have surged, with over 80 studies conducted across 60 centres, including health clinics. Majority of the focus are on chronic kidney diseases, IgA nephropathy, and diabetic kidney disease. Top sites include Hospital Kuala Lumpur, University Malaya Medical Centre, Raja Permaisuri Bainun Hospital, Tengku Ampuan Afzan Hospital, and Pulau Pinang Hospital. This growth underscores the dedication and expertise in advancing kidney health and treatment. Dive into the journey of these rising stars and discover their contributions to advancing kidney health and treatment!

Dr Aida Azlin binti Alias

Nephrologist

Sultan Idris Shah Hospital, Serdang



Areas of Interest in Research

Lupus Nephritis, Focal Segmental Glomerulosclerosis (FSGS), IgA Nephropathy, Membranous Nephropathy, Diabetic Kidney Disease, Chronic Kidney Disease, End Stage Kidney Disease and Critical care Nephrology.

I graduated from UKM in 2006, passed the MRCP UK exam in 2013, completed a Master's in Internal Medicine from UKM in 2014, and finished my Nephrology Fellowship with the MOH Malaysia in 2019. I received a Fellowship from the Royal College of Physicians in 2024.

My research journey began during my master's programme in 2013. Since then, I have participated in 14 clinical trials as a sub-investigator and have numerous journal publications and presentations. I was honoured to be selected as Principal Investigator for a Focal Segmental Glomerulosclerosis (FSGS) study, successfully randomising the first subject in Malaysia, which was recognised by CRM.

With the rise of Diabetic Kidney Disease in Malaysia, my research focuses on slowing disease progression and reducing the need for renal replacement therapy. I am also dedicated to researching other glomerular diseases like Lupus Nephritis, FSGS, IgA Nephropathy, and Membranous Nephropathy to preserve kidney function and extend kidney survival.

Dr Fu Mei Sian

Nephrologist

*Sultanah Aminah Hospital,
Johor Bharu*



Areas of Interest in Research

Chronic kidney disease, diabetic kidney disease, glomerulonephritis and end stage kidney disease.

I graduated from the Russian State Medical University in 2009 and obtained the MRCP(UK) in October 2016. I completed my Master of Internal Medicine at University Malaya in May 2018 and a Post-Graduate Diabetes Diploma at the University of South Wales, UK, under a Merck Foundation scholarship in September 2019. By 2023, I had finished my Nephrology sub-specialty training.

In 2017, I received the Merck Diabetes Award for my work on enhancing medication adherence and cardio-metabolic control in Malaysian type 2 diabetes patients through a smartphone application. The following year, I won the Best Poster Award at the Asia Pacific Nephrology Congress and presented at the Malaysian Congress of Nephrology. My research was published in the Journal of Transplantation in 2019. In 2022, I achieved the Best Poster Award at the World Congress of Nephrology and presented at both the WCN and the International Society of Nephrology.

I believe advancing research in IgA nephropathy, systemic lupus nephritis, diabetic kidney disease, and obesity in kidney patients will need more research in future to delay the disease progression.

Dr Subasni Govindan

Nephrologist

Tuanku Ja'afar Hospital, Seremban



Areas of Interest in Research

General nephrology, chronic kidney disease and glomerulonephritis

My medical career began in 2008 with an MBBS degree from AIMST, Kedah. I started as a houseman at Hospital Tuanku Ampuan Najihah, Kuala Pilah, focusing on Internal Medicine. This interest led me to pursue a Masters in Internal Medicine at the University of Malaya. After nearly three years in Kota Kinabalu as a physician, I specialized in nephrology and completed my Malaysian Board of Nephrology Training in 2022.

During my master's programme, my journey into clinical research began at the University of Malaya. I began conducting clinical research and have since published and presented at local and international platforms. I am also actively involved in TRACK and FIND-CKD clinical trials. My goal as an investigator is to contribute to advancements in kidney disease treatment and prevention, improving patient outcomes through innovative research.

Dr Mohd Ramadhan Bin Mohd Din

Nephrologist

Kuala Lumpur Hospital



Areas of Interest in Research

General nephrology, chronic kidney disease, haemodialysis and peritoneal dialysis

I graduated from the National University of Ireland (University College Dublin) in 2007 and began my medical career with a housemanship at Hospital Tuanku Ampuan Afzan, Kuantan. In 2014, I earned my MRCP (UK) from the Royal College of Physicians, London, followed by a Masters in Internal Medicine at the University of Malaya in 2015. After being gazetted as a physician at Hospital Sultan Haji Ahmad Shah Temerloh, Pahang, I decided to specialize in Nephrology.

In 2019, during my Nephrology training at Hospital Tengku Ampuan Afzan, I started participating in clinical research as a sub-investigator for the VALOR-CKD study. I continued this role at Hospital Tengku Ampuan Rahimah, Klang, in 2020. By 2021, at the Nephrology Department of Hospital Kuala Lumpur, I joined several clinical trials, including ACHIEVE, RESOLVE, CLARION, SIRIUS-LN, and Action3 (Dimerix). Recently, I was appointed Principal Investigator for the STABILIZE-CKD study and the upcoming Baxduo Arctic study, set to start in 2024.

As an investigator, I am actively involved in screening and recruitment patients, support the study team, and provide expertise to ensure patients receive excellent treatments and benefit from clinical trials.

“My goal as an investigator is to contribute to advancements in kidney diseases treatment and prevention outcomes through innovative research”

Dr Subasni Govindan

INFOGRAPHIC

Recruitment Achievements in Sponsored Research 2024

Top Global Recruiter

Sultanah Aminah Hospital
Dr Muhammad Firdaus
Ulcerative Colitis

**Tuanku Ja'afar Hospital
(Top 4)**
Dr Wong Kit Chan
Schizophrenia

Global 1st Recruiter

Sarawak General Hospital
Dr Voon Pei Jye
Non-Small Cell Lung Cancer
(NSCLC)

Queen Elizabeth II Hospital
Dr Liew Hiong Bang
Acute Myocardial Infarction
(AMI)

ASIA 1st Recruiter

Sultan Idris Shah Hospital
Dr Fairul Huda Ibrahim
Active Lupus Nephritis

Pulau Pinang Hospital
Dr Choong Swee Hsia
Melanoma

Kuala Lumpur Hospital
Dr Audi Adwiah
Melanoma

**Tengku Ampuan
Afzan Hospital**
Dr Aishah Ibrahim
Metastatic NSCLC

Malaysia 1st Recruiter

Sultanah Aminah Hospital
Dr Boo Yang Liang
Chronic
Lymphocytic Leukemia

**Pantai Hospital
Kuala Lumpur**
Dr Mastura Md Yusof
• Triple Negative Breast
Cancer
• Breast Cancer
• Endometrial Cancer
• Metastatic Breast Cancer

**University Malaya
Medical Center**
Assoc. Prof. Dr Wan
Zamaniah
Solid Tumors

Dr Wong Chee Kuan
Chronic Obstructive
Pulmonary Disease

Ampang Hospital
Dr Tan Sen Mui
Follicular Lymphoma and
Marginal Zone Lymphoma

Miri Hospital
Dato' Dr Fam Tem Lom
• Cardiovascular Disease
• Dengue

Dr Desmond Samuel
Resistant Hypertension

Tuanku Ja'afar Hospital
Dr Toh See Guan
Beta Thalassemia
Major Anemia

Sultanah Bahiyah Hospital
Dr Zalwani Zainuddin
Functional Dyspepsia

Dr Abd Syukur Abdullah
Heart Failure

**Sultanah Fatimah
Specialist Hospital**
Dr Evelyn Yap Wen Yee
Chronic Inducible Urticaria

Dr Zaid Bin Azhari
Uncontrolled Hypertension

**Queen Elizabeth II
Hospital**
Dr Liew Hiong Bang
Atrial Fibrillation

Pulau Pinang Hospital
Dr Soo Hoo Hwei Fen
Breast Cancer

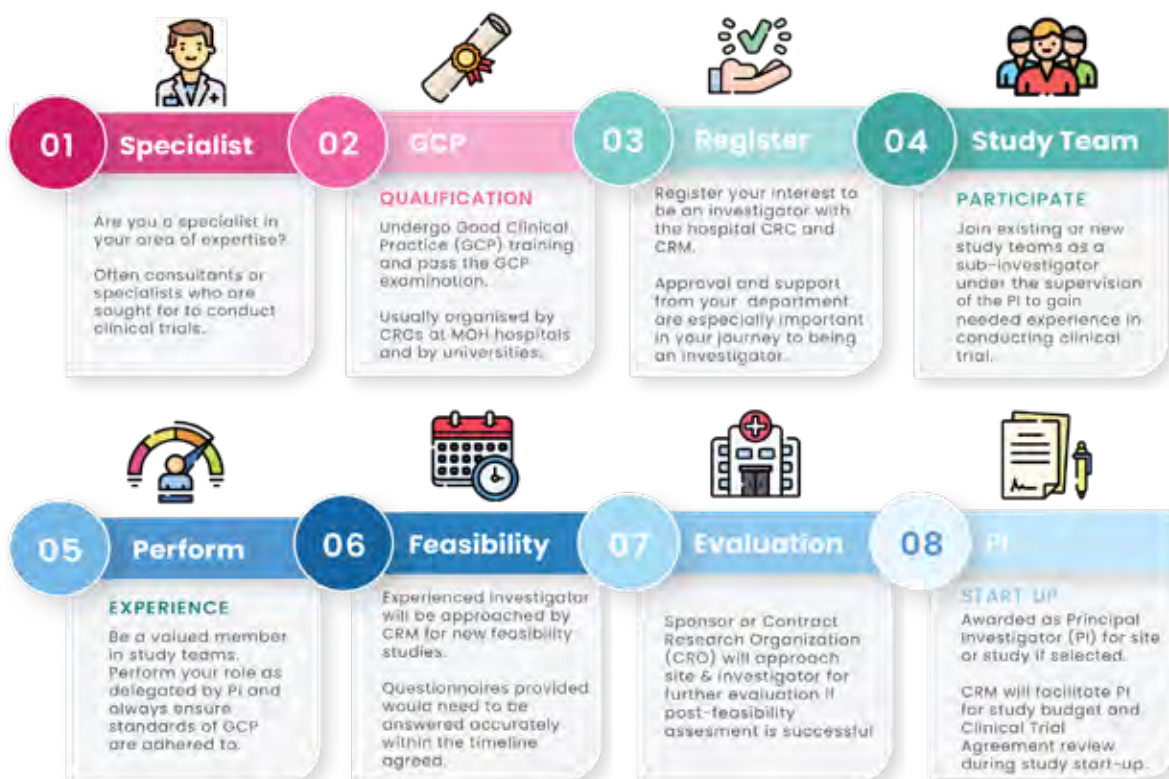
**Tengku Ampuan
Afzan Hospital**
Dr Aishah Ibrahim
Chronic Obstructive
Pulmonary Disease

Seri Manjung Hospital
Dr Lee Li Yuan
Gout Patients
with Hyperuricemia

Sarawak General Hospital
Dr Chua Hock Hin
HIV-1 Infection

Dr Voon Pei Jye
Advanced Solid Tumours
(FIH Biologics)

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

Difficulty in patient
recruitment?

CRM Clinical Trial Advertisement Service addresses your needs



Sponsored Ads



Facebook & Instagram
Platforms



Targeted Audience



Complimentary Ad
Design



Ad Performance
Report Provided



Flexi Package Duration



Ensure data integrity
in clinical trials with

CRM Study Material Destruction Service



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



CRM Provides Certificate of Destruction



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

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

FEATURED SITE

Institut Perubatan Respiratori (IPR)



The Institut Perubatan Respiratori (IPR), an entity under the Ministry of Health Malaysia (MOH), is located on Jalan Pahang, Kuala Lumpur. Established in 1958 as the Tuberculosis Clinic, IPR originally served as a small clinic dedicated to tuberculosis care. In 1960, new building was constructed to support the National Tuberculosis Program and Tuberculosis Hospital. As tuberculosis incidence declined and the scope of respiratory disease services broadened, the Tuberculosis Clinic was renamed as Institut Perubatan Respiratori (IPR) in 1996. Today, IPR functions as a hospital providing comprehensive specialized care across all areas of respiratory medicine, extending beyond tuberculosis management. It offers diagnostic services such as thoracic endoscopy, sleep laboratory, lung function laboratory, and tuberculosis laboratory. Furthermore, IPR serves as the referral centre for Interstitial Lung Disease (ILD) and complex tuberculosis cases, with its local lab being the main culture centre for Mycobacterium culture.

MAIN CLINICAL SERVICES

- Stop Smoking Clinic
- Tuberculosis Management Unit
- Specialist Clinic
 1. General respiratory disease
 2. Interstitial lung disease
 3. Tuberculosis
 4. Respiratory infection (non-tuberculosis)
 5. Lung Cancer
 6. Sleep medicine
 7. COPD and Asthma
 8. Orphan lung disease



FACILITIES

- Respiratory Specialist clinic
- Ward
- High Dependency Unit (HDU)
- Daily Treatment Bed
- In-patient Bed
- Treatment Room
- Centrifuge
- Freezer 20 and 80 degrees Celsius
- Pharmacy
- Sleep Clinic (Polysomnography)
- Lung Function Test (Spirometry and DLco) with cardiopulmonary function
- Bronchoscopy & Thoracoscopy
- Local lab
- Physiology Department

IPR TEAM



HOSPITAL SPECIALTIES BASED ON THERAPEUTIC AREAS

- Pulmonary
- Respiratory

TRIAL SITE BACKGROUND

The Institut Perubatan Respiratori (IPR) began its clinical research endeavours before the year 2000 under the guidance of Datuk Dr. Aziah Ahmad Mahayiddin, managing all research activities internally. All studies conducted are registered under Hospital Kuala Lumpur Clinical Research Centre (HKL CRC), as IPR operates under Hospital Kuala Lumpur. Since 2013, IPR has collaborated with CRM for study coordinator services. Recently, there has been a notable increase in the number of Investigator-Sponsored Research (ISR) projects at IPR. In 2023, the Research Unit (RU) was officially launched, featuring a dedicated team, including a study nurse and a medical officer. This unit is equipped with two consultation rooms, one bed, and a patient bay where various study procedures such as blood collection, physical examinations, and spirometry test are conducted.

Vision:

Establishing Institut Perubatan Respiratori as the primary hub for clinical research in Malaysia.

Mission:

Enhancing patient health through ethical and high-quality clinical research.



STUDY COORDINATORS AT IPR

Nik Nurdiyana has been a study coordinator (SC) at IPR since 2021 and along with Sharifah Alia Amilla since 2023, they have been involved in studies such as idiopathic pulmonary fibrosis, lung cancer, chronic obstructive pulmonary disease, bronchiectasis, asthma, HIV/Hepatitis B and a few other studies as backup SC in HKL.

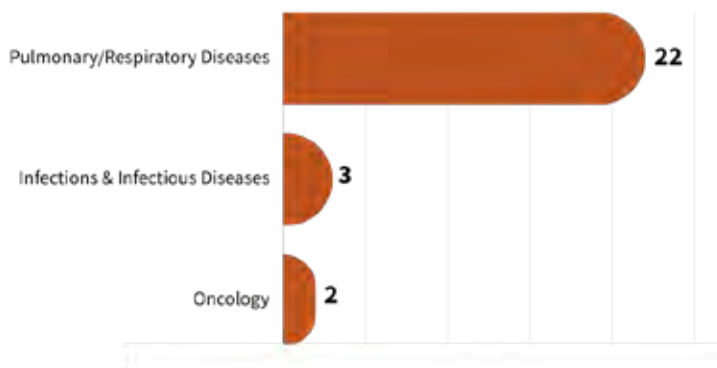


(L-R) Sharifah Alia Amilla Binti Syed Hamid and Nik Nurdiyana Binti Nik Izhar.

SNAPSHOT OF SPONSORED CLINICAL RESEARCH ACTIVITIES IN IPR (2019 - 2024)

Awarded	39
On-going	16
Start-up	7
Closed/Completed	16
Early termination	3

ISR BY THERAPEUTIC AREAS



ACCOMPLISHMENTS IN CLINICAL RESEARCH

Year	Accomplishment
2022	First recruiter in the APAC region for IPF (ENV-IPF-101) - 2022
2023	First recruiter in the APAC region for ELEVATE study
	First recruiter in the SEA region for IPF (1305-0014 FIBRONEER study)
	Top 3 global recruiter and top 2 in the APAC region for ELEVATE study



MEET OUR TEAM

Alvin Bundoi

Associate Regional Manager

*Individual CEO Award 2023 Recipient &
Team CEO Award 2020 Recipient.*



Alvin has 12 years' experience in clinical trial industry, currently based in Hospital Queen Elizabeth as Associate Regional Manager covering East Malaysia A region.

About My Role

My roles and responsibilities are to lead, manage, guide, supervise subordinates and ensure that the clinical trials at sites are conducted efficiently, effectively and with the utmost quality. This involves allocating resources, creating plans and budgets, managing staff responsible for the trials at sites, overseeing trial execution, and managing all sites under my region.

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

When I was a Study Coordinator, conducting the clinical research activities according to the protocol, GCP and SOPs was my day in and out responsibilities, along the years, witnessing patients battle with chronic illness and observing the impact of clinical trials on their treatment has opened my eyes to the crucial role of research in advancing medical knowledge and patient care.

This personal connection to the outcomes of clinical trials inspired me to pursue a career focused on discovering and developing new therapies. The potential to alleviate suffering, improve quality of life, and cure diseases is incredibly motivating.

Now, with my current role, I aim to inspire and motivate study coordinators by ensuring a safe working environment, providing more opportunities, and fostering progressive improvements so they can become even better than I was before.

What has been your greatest learning opportunity in clinical research?

I like the dynamic nature of clinical research field, with its constant advancements and challenges, keeps me engaged and passionate. Being part of CRM team, taught me invaluable lessons in people and project management, teamwork, and the importance of meticulous attention to

detail. In addition, I had the opportunity to work closely with leading researchers, clinicians, and regulatory experts, which broadened my understanding of the clinical trial process.

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

Integrity is paramount as it ensures all aspects of the process in any roles, by upholding integrity, it's not only building trust and respect but also contributes to a positive work environment and organizational culture where employees feel valued and motivated to perform at their best. Embracing integrity also means being open to feedback, learning from mistakes, and continuously improving practices to uphold the highest standards.

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

It is the combination of purposeful work with the team, collaboration, continuous improvements, and ethical responsibility that keeps me motivated and engaged in my daily work.



Alvin with his East Malaysia A Team



Cheng Shu Hui
Senior Feasibility Specialist

Roles and Responsibilities

I started my clinical research journey with CRM in 2021 as a feasibility specialist, later advancing to senior feasibility specialist. In this role, I serve as the primary contact for feasibility enquiries from sponsors, CROs, investigators, and site personnel. My duties include delegating, managing, coordinating, and overseeing feasibility projects across various therapeutic areas, ensuring timely responses to clients.

My team and I review scientific literature and clinical practice guidelines, gathering information on target indications and investigator feedback to ensure high-quality feasibility reporting. Each year, our Feasibility Team conducts 'Nurturing New Talents in Sponsored Research' workshops to foster interest and understanding of industry-sponsored research among investigators and study teams, aiming to promote the growth of principal investigators in the country. Additionally, I am also a member of the Code of Conduct (COC) Committee.

How do feasibility assessments impact clinical trials, and what are the perspectives from both the site and the sponsor?

Feasibility assessments are vital in planning and executing clinical trials. They evaluate whether a trial can be successfully conducted at a specific site or within a region, ensuring selected sites are well-equipped for the study. For sites, these assessments confirm they can meet trial demands according to the study design and inclusion/exclusion criteria without overextending resources, including manpower and budget. For sponsors, they aid in selecting the right sites, managing costs, ensuring compliance, and maintaining data quality. This collaborative process enhances the overall efficiency and effectiveness of clinical trials, leading to more reliable and timely outcomes.

How do you manage feasibility challenges and ensure smooth trial operations?

Managing feasibility challenges and ensuring smooth trial operations hinge on strategic planning, detailed analysis, effective communication, and proactive support. We use the CRMx portal system, which includes all industry-sponsored research at MOH sites and a comprehensive database of potential investigators from MOH, MOHE, and private sectors. This portal allows us to thoroughly evaluate trial sites and investigators by

assessing their infrastructure, patient population, and past trial performance. We also analyze historical data to identify trends, spot potential issues, and optimize site selection.

We maintain regular communication with sites to provide updates, gather feedback, and address concerns promptly. Building strong, collaborative relationships with site investigators, coordinators, and other key stakeholders fosters a cooperative environment. By leveraging these strategies, feasibility specialists can enhance site performance, optimize patient recruitment, ensure regulatory compliance, and maintain high-quality data, ultimately contributing to the success of clinical trials.

What part of your role do you find most rewarding or challenging?

As a feasibility specialist, one of the most rewarding aspects of my role is the sense of accomplishment and teamwork that comes from meeting tight deadlines or urgent sponsor requests. Successfully identifying suitable sites, conducting rapid feasibility assessments under tight timelines, and seeing the study progress from site selection to activation showcases our team's expertise and resilience. However, this can also be one of the most challenging parts, as it requires balancing thoroughness and speed, managing stress, and ensuring all stakeholders are aligned and responsive, all while maintaining the quality and integrity of the feasibility study process.

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

I stay motivated through a blend of appreciation from sponsors/CROs, support from colleagues, and personal well-being practices like brief yoga sessions. Recognition from sponsors validates our hard work, boosting morale and commitment. My colleagues' collaborative and positive spirit creates an energizing work environment, while yoga and mindfulness exercises help maintain mental clarity and reduce stress. This combination keeps me motivated and passionate about my role every day.

Feasibility Assessments: What Investigators Need to Know

Journal for Clinical Studies, Volume 16, Issue 1

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

The feasibility of clinical trial involves a thorough assessment of the potential and practicality of conducting a particular trial within a specified geographic area to ensure a project's success in terms of timeline, target achievement, cost management, and various other essential factors. The extent of feasibility outreach can constitute an initial assessment phase that provides a preliminary understanding of the disease prevalence and standard of care. In contrast, an extensive feasibility analysis encompasses patient criteria, site capabilities, regulatory requirements, and potential execution challenges, thus enabling informed decision-making while paving the way for a successful clinical trial execution and delivery.¹ Clinical Research Malaysia (CRM) provides a centralised feasibility assessment to sponsors and contract research organisations (CROs) to match clinical trials with the right investigators and sites in Malaysia. CRM provides reliable insights and up-to-date information that covers the hospitals in the public, private, and academia to ensure that potential centres and institutions are tapped into the study.²

This article offers key insights to investigators, underscoring the importance of feasibility assessments, the impact of feasibility on successful clinical trials, and recommendations for improving feasibility responses.

Feasibility Growth and Its Importance

Over the period spanning from 2018 to 2023, the growth of feasibilities conducted by CRM has been significant (Figure 1). In line with this, there has also been an increasing number of sponsors and Contract Research Organisations (CROs) conducting feasibility studies through CRM. Based on the annual customer satisfaction survey reported in the CRM Annual Report 2022, 94% of the respondents rated “good” and “very good” for CRM’s complimentary feasibility service.

There are a few components that should be considered by clinical investigators when responding to feasibility questionnaires, such as population profile and access,³ facilities and equipment accessibility, and investigators’ experience.¹ Usually, each of the components has a weight assigned based on the sponsors’ evaluation of the site’s strengths and weaknesses and allows for objective comparison. Hence, due consideration should be given to each of the components in completing the questionnaires to meet the feasibility objective and facilitate site selection.

Estimating Potential Patient Population

A vital aspect of feasibility assessment is identifying the availability of patients with a certain disease condition specific to a particular trial. Investigators’ considerations encompass a thorough review of the study design, inclusion/exclusion criteria for patient recruitment, the current standard of care, frequency of visits, invasiveness level of the trial, and the provision of reimbursement for study-related procedures.¹ Furthermore, correctly identifying the available patient pool, while exercising caution on underestimation, and ensuring realistic projections of patient numbers are crucial aspects to consider.

References from Clinical Practice Guidelines (CPG), up-to-date patient registries,⁴ and the availability of databases such as the Malaysian Health Data Warehouse (MyHDW) platform, could provide vital data 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 target set.



Figure 1: Total full feasibility and pre-feasibility from 2018 - 2023

Resources and Infrastructure

Assessing infrastructure in healthcare institutions is crucial in determining the site's ability to conduct clinical trials.⁵ A thorough evaluation enables sponsors and investigators to anticipate and proactively address challenges during the feasibility stage. Having basic and adequate facilities such as freezer and fridge for investigational product storage and centrifuge with regular calibration taking place, will increase the chances of sites being selected during the feasibility assessment. Considering Malaysia's resource allocation and population distribution, certain sites may lack essential diagnostic capabilities or long waiting times at diagnostic units. The sites' readiness to utilize outsourcing services offers a valuable alternative for obtaining timely results. In addition, it also helps in mitigating the prolonged turnaround time of test results and alleviates overcrowding issues at public hospital laboratories. CRM provides the support to connect sponsors and CROs for the outsourcing services to ensure a successful trial.

Investigators' Experience and Competing Studies

Investigators' experience and their familiarity with the study protocols are vital for successful studies.⁶ In addition, identifying competing studies involving similar patient populations is crucial for patient recruitment. Investigators are encouraged to share their trial experience and disclose any ongoing or planned trials within the same patient pool at a particular locality. This could prevent challenges in recruiting patients for different trials which taps into the same patient pool especially if both trials are taking place at the same time. CRM continuously provides training to the study teams to uphold the quality of trial conduct and adherence to the protocol. The trainings include Nurturing New Talents in Sponsored Research, GCP refresher courses, Protocol Compliance Workshop, and Patient Recruitment and Retention Workshops.

Challenges and Strategies

One of the challenges in meeting Sponsors' requirements includes short timelines given to investigators to complete feasibility questionnaires, especially if the study is under the bidding stage by a CRO or if it's a rescue study for an ongoing trial that is already happening in other parts of the world. Sponsors may also set short timelines to meet specific business objectives and address seasonal considerations, such as disease outbreaks, which require rapid trial initiation and completion. With digitalisation playing a larger role in clinical research, sponsors and CROs are introducing new digital platforms to implement feasibility assessments. Unfamiliarity with the use of these platforms among investigators also poses challenges in responding to feasibility in a timely manner. To address this, CRM feasibility team and onsite study coordinators support the investigator in completing the feasibility questionnaire, with input from investigators. Guidelines on navigating the feasibility platform and support in gathering information from other departments, such as the laboratory and pharmacy are

provided. This collaborative effort expedites the feasibility process, leading to quicker site start-up if the sites are selected.

Other strategies aimed at improving feasibility timelines include the use of e-signatures in Confidential Disclosure Agreements (CDA)⁸ and utilising online questionnaires/surveys from sponsors. E-signature is legally recognised under the Electronic Commerce Act 2006 (ECA) in Malaysia. E-signature offers flexibility that can aid in recordkeeping, improve efficiency and deadlines, and reduce the overall timeline for feasibility assessment. The incorporation of e-signatures and online surveys aligns with CRM and the industry's focus on operational efficiency in clinical trials.

Conclusion

Details and information shared by investigators in feasibility assessments carry a huge weight in sponsors' decisions in site selection. Significant aspects including the availability of the patient pool, basic facilities, relevant investigator experience, and upcoming competing trials will also ensure that they can deliver the trial and meet the expectations of sponsors. Feasibility assessments enable investigators to anticipate and address challenges in clinical trials, which could facilitate resource utilisation and the development of effective strategies in trial initiation. At the end of the day, a good feasibility assessment and response translates into successful clinical trials. CRM continuously supports investigators in feasibility assessments and endeavours to ease communication between the investigator and sponsor throughout the process.

References

1. Rajadhyaksha V. Conducting feasibilities in clinical trials: an investment to ensure a good study. *Perspect Clin Res*. 2010 Jul;1(3):106-9. PMID: 21814631; PMCID: PMC3146075.
2. Ooi, A.J.A & Khairul, F.K. A Unique Model to Accelerate Industry-Sponsored Research in Malaysia. *Journal for Clinical Studies*. 11(1), 24-27 (2019).
3. Identifying and selecting a clinical trial for your practice. *J Oncol Pract*. 2008 Jan;4(1):27-8. doi: 10.1200/JOP.0814602. PMID: 20859441; PMCID: PMC2793943.
4. Christian J, Dasgupta N, Jordan M, et al. Digital Health and Patient Registries: Today, Tomorrow, and the Future. In: Gliklich RE, Dreyer NA, Leavy MB, et al., editors. *21st Century Patient Registries: Registries for Evaluating Patient Outcomes: A User's Guide: 3rd Edition, Addendum* [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2018 Mar. 3. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK493822/>
5. Buse JB, Austin CP, Johnston SC, Lewis-Hall F, March AN, Shore CK, Tenaerts P, Rutter JL. A framework for assessing clinical trial site readiness. *J Clin Transl Sci*. 2023 May 8;7(1):e151. doi: 10.1017/cts.2023.541. PMID: 37456265; PMCID: PMC10346039.
6. Cimino J, Braun C. Design a Clinical Research Protocol: Influence of Real- World Setting. *Healthcare (Basel)*. 2023 Aug 10;11(16):2254. doi: 10.3390/healthcare11162254. PMID: 37628452; PMCID: PMC10454664.
7. M.Murad I.M, Johari, N.H, Kuppusamy V., and Yeoh J. CRM Study Coordinators –Making a Difference in Clinical TrialConduct in Malaysia, *Journal for Clinical Studies Volume 15 Issue 1*.
8. Roslan H.N.S, A. Muis N.S, and A. Rahman N.A Impact of Electronic Signature Towards Clinical Trial Agreements, *Journal for Clinical Studies, Volume 14 Issue 6*

CRM IN PHOTOS



CRM with Dr Jane Olivia Lorens, Head of Clinical Research, Siloam Hospital, Indonesia.

7
May



CRM met with Prof Danny Soon, CEO of the Consortium for Clinical Research and Innovation Singapore, and the SCRI team. The introductory meeting aimed to understand both organisations.

13
May



CRM met with Sansure Biotech, an IVD diagnostic company from China. Discussion was on potential diagnostic studies in HPV, Dengue, and Hepatitis.

21
May



CRM had an engaging meeting with the Hemophilia Society of Malaysia to explore potential collaboration on patient recruitment to raise awareness of clinical trials among patients.

13
June



CRM met IQVIA leaders, including Cynthia Verst, President of R&D Solutions; Rajneel Patel, Vice President of Clinical Operations at DIA2024 Global Annual Meeting in San Diego.

18
June



CRM met with Celero CEO, Adham Rezk. Discussion was mainly on sharing CRM's expertise in conducting clinical research.

21
June



Geraldine Tong from The Star Media Group Berhad's Focus section of the Sunday edition interviewed CRM CEO, Dr. Akhmal Yusof at CRM office.

27
June



CRM met with Martin Lim, CEO of Onward Health Research.

3
July



CRM met with Dr Yolanda from St George's University, along with Shelly and Jean from Wantai Biopharm.

4
July



CRM had a catch-up meet with CSI Medical Research (A ClinChoice Company).

4
July



CRM had engaging meet with SW Strategies team led by Jose Raymond, the Founder & Managing Director.

11
July



CRM had touch-base meet with UMMC team led by Prof Dr Maznah (Head of Research, Development & Innovation).

11
July

CRM IN PHOTOS



CRM visited Johnson & Johnson's office and connected with the Global Clinical Operations team, including APAC Global VP Koichi Nishijo and SEA, Australia & New Zealand Cluster/Country Head Anna Lam.

11
July



Introductory meet with Kent Lee, Director of Research of Inspire Medical Systems.

12
July



CRM met with Merck KgaA team. Discussion was focused on Malaysia's delivery on global studies, CRM's initiatives in upscaling the clinical research talents in Malaysia and the developments in Merck Oncology pipeline.

15
July



CRM met with Yayasan Jantung Malaysia (YJM) to collaborate on raising clinical trial awareness among YJM's audience and to understand their initiatives and goals for improving cardiovascular health.

16
July



CRM had engaging meet with Datatxt: Nama team about media monitoring in enhancing clinical research strategies and outcomes.

16
July



CRM connect with Rudi Paye (Strategy & Operations Director) of DNDi, sharing on CRM's role in sponsored research as well as on its ongoing initiatives.

17
July



CRM and Novartis team met to discuss on Novartis's pipelines, enhancing Malaysia's site profile through feasibility and patient recruitment specialists.

23
July



CRM touch base meet with KPJ Healthcare team led by Prof Emeritus Dato' Dr Lokman, Vice Chancellor of KPJ Healthcare University College.

24
July



CRM and Columbia Asia Bukit Rimau had an engaging discussion centred on potential collaboration to utilise CRM's services and strategies to attract more clinical trial opportunities.

25
July



CRM visited the National Kidney Foundation of Malaysia to explore collaborative opportunities.

25
July



CRM met with Oncoshot CEO, Dr Huren and CCO, Mr Chua Chee Yong to discuss on harnessing the platform for patient cohort visibility.

29
July



CRM met with Isabelle Niekrake and Agnes Seah from the Embassy of the Kingdom of the Netherlands to discuss CRM's role and explore collaboration opportunities between Malaysia and the Netherlands.

31
July

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