BY CLINICAL RESEARCH MALAYSIA

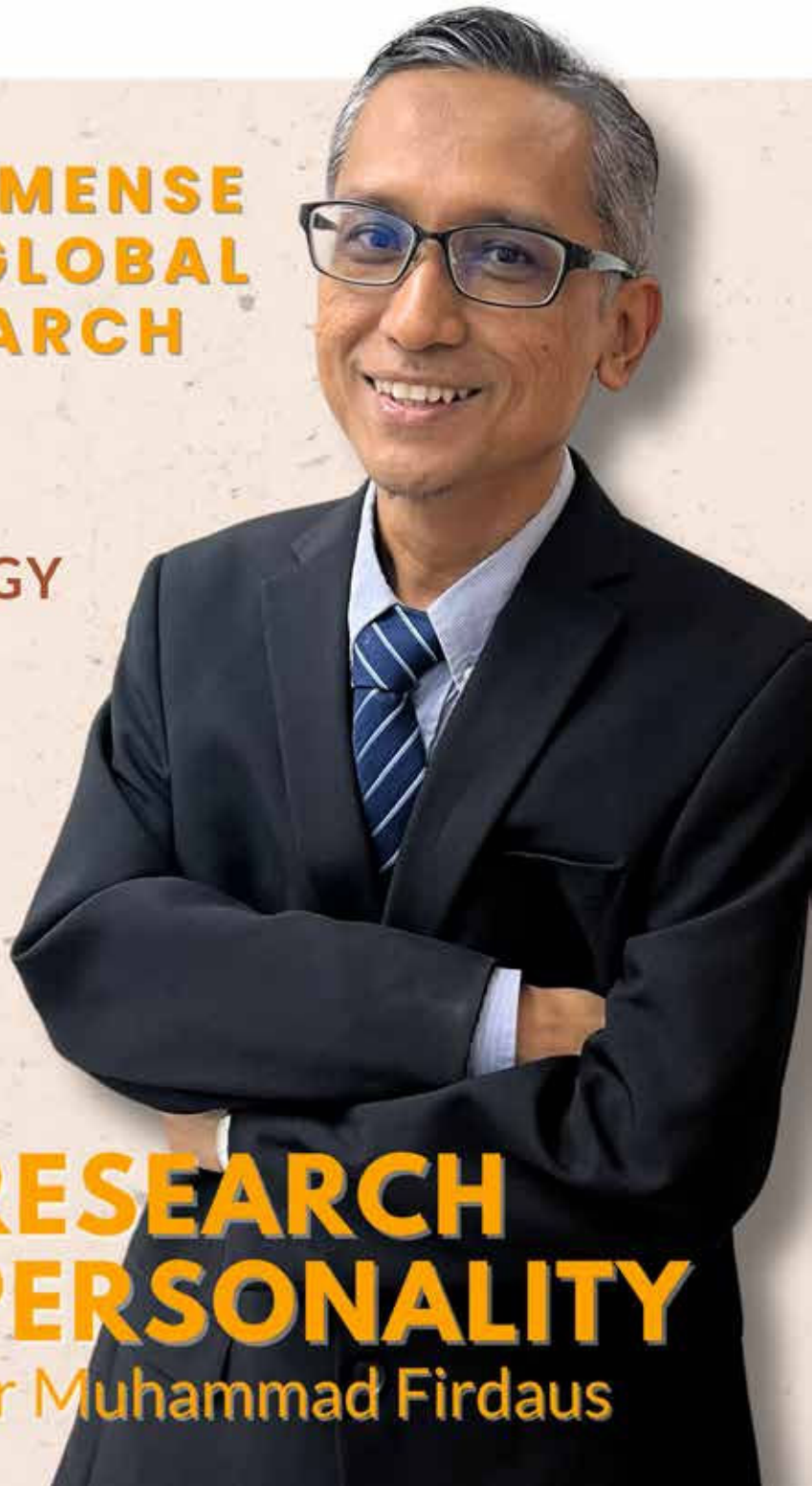
CRM Bulletin

ISSUE 27 | Jan - Apr 2024

MALAYSIA'S IMMENSE POTENTIAL IN GLOBAL CLINICAL RESEARCH

RISING STARS IN GASTROENTEROLOGY

FEATURED SITE
Sultanah Aminah Hospital



RESEARCH PERSONALITY
Dr Muhammad Firdaus

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.

CRM
CLINICAL RESEARCH MALAYSIA
Your Global Solutions in One Nation

From The CEO's Desk

Warmest welcome to CRM Bulletin 27!

The remarkable achievements made in 2023 have translated into tangible results, as reflected in our significant contribution of RM1.16 billion to Malaysia's Gross National Income (GNI) accumulated since 2012. What a remarkable way to kick off the first quarter of 2024 with numerous triumphs! CRM is committed to keep thriving and bringing steps closer to target goals of making Malaysia as a preferred hub for clinical research in Asia following our vision 2033.

We engaged impactful collaborations with international and local stakeholders, forging strategic partnerships. A standout moment was the signing of the Memorandum of Understanding (MoU) with The Chinese University of Hong Kong (CUHK), marking a significant milestone detailed in this bulletin issue.

Adding to our excitement, we successfully launched the Centre of Excellence (CoE), programme designed to kickstart careers in clinical trials and underscore our commitment to nurturing the next generation of clinical research professionals. We also proud to announce the release of our CRM Annual Report 2023, which showcases our nation's remarkable achievements and milestones in clinical trials, highlighting the sponsored clinical research accomplishments achieved under CRM's guiding principles of Humanity, Stability, and Sustainability.

As we embark on the journey of 2024, I am immensely proud of the strides we have made in advancing clinical research in Malaysia. The achievements of 2023, highlighted in this report, underscore our unwavering commitment to excellence and innovation in the field. I extend my deepest gratitude to our partners, stakeholders, and the dedicated teams at CRM for their tireless efforts in driving progress. Together, we will continue to push boundaries, foster collaborations, and make significant contributions to the advancement of healthcare and research in our nation 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

CRM's Board of Directors Meeting

5 January 2024 – CRM concluded its Board of Directors' Meeting of 2023, thanking YB Datuk Seri Dr. Haji Dzulkefly Ahmad and BOD members for their support in executing Vision 2033 and advancing the organisation's 10-year plan for clinical research.

MRCT Seminar by PMDA Japan

23-26 January 2024 – CRM's Senior BD Manager, Asha Thanabalan participated along with team from National Pharmaceutical Regulatory Agency in the Multi-Regional Clinical Trials (MRCT) Seminar organised by PMDA with National Cancer Centre Japan. The program was aimed to engage representatives from academia and industry on the planning and evaluation of MRCT in the region.

CRM's Educational Engagement with University of Nottingham

7 February 2024 – CRM's Legal lead, Ms Nurul Atiqah spoke in an engaging educational session with Biomedical Science students at University of Nottingham, on Healthcare Laws in Malaysia and Code of Medical Ethics, with the aim to highlight awareness to students on the governing laws on healthcare.

I AM AWARE 2024

14-15 February & 6-7 March 2024 – CRM successfully conducted 2 I AM AWARE Roadshows at Sultan Idris Shah Serdang Hospital and Putrajaya Hospital. CRM aspires to elevate the awareness level of clinical trials to the general public and patients and to address any questions or misconceptions regarding clinical trials that they may have.

1st Patient Recruitment & Retention Workshop

14 February 2024 – CRM's Clinical Operations team successfully conducted their first Patient Recruitment & Retention workshop in 2024 with participants from both internal and external stakeholders. We hope that the methods and strategies shared during the workshop will prove beneficial to all attendees.

ASPIRE 2024

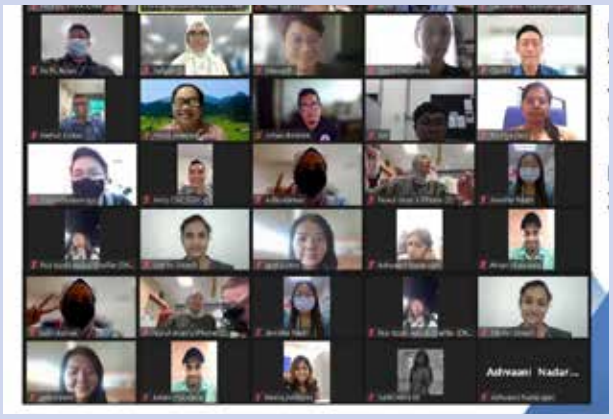
25 February 2024 – CRM Chief Executive Officer, Dr Akhmal Yusof spoke at Access, Pharmaceutical & Health Economics Conference (ASPIRE) on Elevating Malaysia's Role in Global Clinical Trials - Collaborative Pathways for Advancement.

Nurturing New Talents in Sponsored Research

8 March 2024 – CRM's Feasibility team successfully held their first Nurturing New Talents (NNT) workshop at National Cancer Institute (IKN) in 2024. The program also featured speakers Dr Janet Hong (Hospital Putrajaya) and Ms Luisiawati (MSD) who shared valuable insights on investigator and sponsor's role in a clinical trial

Senior Leadership Team in Sarawak

8 March 2024 – CRM's Senior Leadership Team (SLT) was at Clinical Research Centre SGH, connecting with both Dr Alan Fong (Head of CRC) & Dr Diana Foo. The team in SGH has been consistently delivering in sponsored clinical trials, especially in early phase and oncology trials, making this among the top sites in Malaysia.



Good Clinical Practice Refresher Workshop

20 March 2024 – The first Virtual Good Clinical Practice (GCPR) Refresher Workshop of 2024. The session aim to benefit attendees on their path to becoming investigators.

Center of Excellence (CoE) Program

22 March 2024 - The inaugural program, Centre of Excellence Programme is designed to serve as the cornerstone for participants to kickstart their careers in clinical trials. The March batch intake will be undergoing a 12-week module program which includes theory and hands-on training

CRM's Newly Renovated Office at Menara Suezcap

9 April 2024 - Newly renovated office at Level 25 of Menara Suezcap caters to the Centre of Excellence program as well as training and development needs of CRM. The office also is the working premise of CRM's clinical operations HQ team, which has recently expanded to support the CoE program.

Visit from Datuk Amar Prof Dr Sim Kui Huan at CRM Office

17 April 2024 - Datuk Amar Prof Dr. Sim KH visited the CRM Office to motivate the team in delivering clinical trials with excellence. Located adjacent to Sarawak General Hospital in Kuching, the CRM Office provides a conducive working environment for Study Coordinators supporting SGH investigators.

10th EA-TOPIC in Taipei: Strengthening Early Phase Clinical Trials Collaboration.

20 April 2024 - CRM participated in the 10th East Asia Oncology Phase I Trials Conference (EA-TOPIC) in Taipei. Congratulations to Prof. James Yang for a successful program. CRM continues to collaborate with East Asian partners to enhance our early phase clinical trial capabilities. During the conference, Dr Voon Pei Jye (medical oncologist, Sarawak General Hospital) also presented on Malaysia's journey & advancement in First-in Human trials.

CRM Study Coordinators Train at Top Taiwan Phase 1 Centre

22 April 2024 - CRM Study Coordinators Li Fang & Erfan of Sarawak General Hospital, underwent a 1-week attachment at Taiwan's top Phase 1 Centre in National Taiwan University Hospital. Stay tuned for more under CRM's Phase I Realisation Project 2.0!

CRM is on BFM 89.9!

26 April 2024 – CRM Chief Executive Officer, Dr Akhmal Yusof and PhAMA Board Member, Dr Mohamed Elwakil had an insightful interview session at BFM 89.9 Station discussing Malaysia's capabilities in becoming a regional hub for clinical trials.

Company Meeting 2024/1

29 April 2024 – CRM had its first 2024 company meeting, discussing the current updates and progress of the first quarter of 2024. CRM hopes to deliver more in terms of making Malaysia as the preferred hub for clinical research and serving the healthcare system in Malaysia.

SPOTLIGHT FEATURE

Clinical Research Excellence in Early Phase & People Development

PUTRAJAYA, 4 January 2024 - Roche Pharmaceuticals has chosen Sarawak General Hospital as Site for a First-in-Human (FIH) clinical trial in Malaysia, making it the first top multinational company to conduct FIH trials under a rheumatology indication in the country. This milestone underscores Malaysia's growing clinical trial capabilities in Asia, achieved within just two years following the completion of Clinical Research Malaysia's (CRM) Phase 1 Realisation Project (P1RP), which facilitated the establishment of the FIH ecosystem. The announcement was made during CRM's Clinical Research Excellence in Early Phase and People Development event, officiated by Minister of Health Datuk Seri Dr. Dzulkefly Ahmad. Malaysia will now be the seventh country included in the study and the first within the Asia Pacific region, joining other global sites in Europe and South Africa.

"Malaysia's clinical trial ecosystem has developed rapidly with over 2300 clinical research conducted since 2012. CRM through its P1RP initiative have overseen the development of the country's early phase ecosystem, to enable safe and regulated conduct of early phase research especially FIH trials. Following the completion of P1RP in 2021, Malaysia has conducted one FIH and two First-in-Patient studies, with Roche's study being the first FIH in Malaysia under a rheumatology indication," said Datuk Seri Dr Dzulkefly during his speech.

In conjunction with this groundbreaking event, Clinical Research Malaysia (CRM) and the Pharmaceutical Association of Malaysia (PhAMA) have entered a strategic partnership to propel the development of clinical research talents and skills in Malaysia. The MoU was signed by Dr Akhmal Yusof, CEO of CRM, and Ms Kam Ai Teng, President of PhAMA, and witnessed by Minister of Health Datuk Seri Dr Dzulkefly Ahmad. This outlines PhAMA's commitment to supporting CRM through the provision of proteges on an annual basis for the next three years. This collaboration will be facilitated through CRM's Centre of Excellence (CoE), which focuses on enhancing the nation's clinical research capabilities by building skilled study coordinators profession. The initiative aligns with the Pharmaceutical Sector's Research and Development (R&D) objectives outlined in the New Industrial Master Plan (NIMP) 2030.

Ms. Kam Ai Teng, President of PhAMA, echoed this sentiment, highlighting the crucial role of innovation and research in the pharmaceutical industry. "PhAMA is enthusiastic about contributing to the clinical research landscape in Malaysia. The fact that the top five sponsors of new sponsored research in the last five years are all PhAMA members attests to our steadfast commitment to advancing healthcare through research and development."

Dengue Research Visibility Day

SELANGOR, 4 March 2024 - The Ministry of Health (MOH) through the Institute of Medical Research (IMR) has organised the Dengue Research Visibility Day 2024 earlier today, in collaboration with the Drugs for Neglected Diseases initiative (DNDi) and Clinical Research Malaysia (CRM). The inaugural event called for shared commitment of nations and organisations in addressing the pressing global health challenge posed by dengue. The event was officiated by YB Datuk Seri Dr. Dzulkefly Ahmad, Minister of Health and also attended by YB Dato Lukanisman bin Awang Sauni, Deputy Minister of Health.

Dengue is the most widely distributed and rapidly spreading mosquito-borne infectious disease, with an estimated 390 million infections each year in over 100 countries. The disease is exacerbated by climate change, rapid urbanisation, and population growth. Half of the world's population is at risk of dengue, which is classified by the World Health Organization (WHO) as one of the top ten threats to public health. Despite its prevalence, there is currently no specific treatment, leaving individuals at risk of developing severe and potentially fatal complications.

The collaborative efforts of the Ministry of Health of Malaysia with DNDi and other dengue-endemic countries are encapsulated in the Dengue Alliance, a global partnership launched in 2022, with the unique feature of endemic countries, including Malaysia, Thailand, India and Brazil, taking a leadership role in therapeutic and diagnostic research endeavours. The alliance is dedicated to developing affordable and accessible treatments for dengue works on joint projects, advancing pre-clinical development of new drug candidates, and conducting clinical trials to test the most promising ones. It includes the Faculty of Medicine Siriraj Hospital, Mahidol University, Thailand; the Translational Health Science and Technology Institute (THSTI), India; the Oswaldo Cruz Foundation (Fiocruz), Brazil; and the Universidade Federal de Minas Gerais (UFMG), Brazil.

"Dengue, a climate-sensitive neglected tropical disease, demands immediate attention. Our collaborative approach with endemic countries through the Dengue Alliance is revolutionary, allowing these countries to lead their own research efforts to find urgently needed treatments for dengue," said Jean-Michel Piedagnel, director of DNDi South-East Asia. Within Malaysia, CRM and DNDi are collaborating with Malaysia's foremost research institutes, Institute for Medical Research (IMR) and the Institute for Clinical Research (ICR) on collaborative initiatives aimed at advancing preclinical investigations of potential treatments, testing the efficacy of several repurposed drug candidates, and implementing clinical trials of the most promising ones. Simultaneously, the organisations will coordinate efforts to address knowledge gaps and expedite clinical research to meet unmet needs.

"The primary focus is on conducting preclinical studies and clinical trials with the aim of bringing cost-effective and accessible treatments to fruition within the next five years. Let us hope for another success story played by the Dengue Alliance in developing a new elixir of hope for treatment of dengue patients, alike our previous successful joint efforts in developing together a safe and affordable hepatitis C treatment," said Datuk Seri Dr Dzulkefly Ahmad, Health Minister of Malaysia.

Malaysia's Record-Breaking Success In Sponsored Clinical Research

PUTRAJAYA, 22 April 2024 - Malaysia has achieved yet another remarkable milestone in sponsored clinical research, surpassing its target and previous years' accomplishments, as highlighted in Clinical Research Malaysia's (CRM) Annual Report 2023. This achievement was unveiled during the CRM Annual Report launch at the Ministry of Health (MOH) office, by the Minister of Health, YB Datuk Seri Dr Dzulkefly Ahmad.

The annual report outlined 276 newly sponsored clinical research studies in the country, representing the highest number recorded since the organization's establishment in 2012. In 2023, Malaysia rose to second place within the Southeast Asia region in terms of the number of global industry-sponsored studies. These record-breaking figures are also mirrored in the Gross National Income, contributing to a cumulative value of RM1.16 billion generated from sponsored research since 2012.

Malaysia's early phase research reported significant breakthroughs, with both First-in-Human (FIH) accredited centres in Malaysia, Ampang Hospital having initiated its first First-In-Patient study last November 2023, and Sarawak General Hospital having received international recognition for successfully conducting a global FIH study. Following these accomplishments, Malaysia is in the radar of global top biopharmaceuticals, with two new FIH clinical trial slated to initiate by mid-2024 at Sarawak General Hospital in Systemic Lupus Erythematosus (sponsored by Roche Pharmaceuticals) and solid tumour (sponsored by AstraZeneca) respectively.

"Following our track record in trial conduct, the pharmaceutical industry is now not only viewing Malaysia as a trial location, but also as a regional base for clinical research operations. I am confident that the positioning of these hubs will greatly benefit the nation's clinical research workforce and I look forward to hearing more borne from our successful industrial collaborations." said Datuk Seri Dr Dzulkefly Ahmad, Minister of Health Malaysia.

Clinical Research Malaysia (CRM) and The Chinese University of Hong Kong (CUHK) also entered a landmark collaboration, following the Annual Report launch. The Memorandum of Understanding (MoU) was signed by Dr Akhmal Yusof, Chief Executive Officer of CRM, and Professor Juliana Chan, Director of the Clinical Research Management Officer of CUHK, and was witnessed by Datuk Seri Dr Dzulkefly Ahmad. This MoU underscores joint efforts in the areas of clinical, academic, and research opportunities at both organizations as it further consolidates the efforts led to upskilling the researchers as well as in driving knowledge exchange in clinical research. Both CRM and CUHK are dedicated to promoting and facilitating collaboration, innovation, and clinical research between both nations.

RESEARCH PERSONALITY

DR MUHAMMAD FIRDAUS BIN MD SALLEH

CONSULTANT GASTROENTEROLOGIST & HEPATOLOGIST, PHYSICIAN, SULTANAH AMINAH HOSPITAL

About Dr Muhammad Firdaus

He graduated from the National University of Malaysia (UKM) and has been actively involved in gastroenterology clinical trials as the sole consultant at Hospital Sultanah Aminah Johor Bahru since 2019. His primary focus is Investigator-Initiated Research (IIR) and Investigator-Sponsored Research (ISR), particularly in Inflammatory Bowel Disease (IBD). Alongside three other Gastroenterologists, he supervises and coordinates gastroenterology and hepatology training and services for the state of Johor.

Can you tell me the beginning of your journey as a principal investigator?

Back then, I had little knowledge about clinical trials, and I perceived them as challenging, rigid, and even dull. My trainer told me as clinician, doing research and conducting clinical trials are inevitable. The words never sparked my mind yet until I came back from my training overseas in 2019 and found compilation of previous studies on a drug for IBD which is now currently being used in treatment worldwide. This discovery ignited a desire within me—an indescribable satisfaction knowing that I could contribute to such groundbreaking research. It was then that I realised I wanted to be part of the team assessing a drug's safety and effectiveness before its introduction to the market.

What drives you to conduct clinical trials?

Due to the limitations of resources for advanced therapy in IBD, it gives me hope to be able to provide opportunities for my patients to access a therapy that is ahead of its introduction to others. This allows me to monitor and observe improvements, which further fuels my hope and drive.

What is your personal vision as an investigator?

I aspire to engage in clinical trials and mentor as many trainees as possible. My goal is to make significant contributions to the community and be part of the history of new treatments or strategies that benefit patients safely and effectively. I envision a future where clinical research becomes a subject of interest for most clinicians.

In Gastroenterology, what are the changes you want to observe?

I wish to see more doctors join in Gastroenterology and play various roles in endoscopy, not only diagnostics but also therapeutics, to provide alternatives for patients instead of surgeries. I would like to see more affordable and effective treatment options available for patients with inflammatory bowel disease.

DR MUHAMMAD FIRDAUS'S ROADMAP TO INVESTIGATOR

2002
Graduated with Medical Degree from Universiti Kebangsaan Malaysia

2009
Started being involved in gastroenterology clinical trials

2012
MRCP (UK) & Membership of the Royal College of Physicians (MRCP)

2015
First role as Principal Investigator in Investigator-Initiated Research (IIR)

2019
Underwent Gastroenterology Fellowship Training Commitee, Ministry of Health

Recruitment Achievement

2023

- Malaysia's 1st Recruiter in Ulcerative Colitis Study
- Top Malaysia's Recruiter in Chron's Disease Study

2024

- Top Global Recruiter in Ulcerative Colitis Study

Clinical Research Experience

- Sub-investigator in 11 studies
- Principal Investigator in 14 studies

- 5 Clinical Audits Presentations
- 24 Publications

Areas of Interest in Research

Inflammatory Bowel Disease (IBD)

RISING STARS IN GASTROENTEROLOGY

Since 2012, the field of Gastroenterology has experienced significant growth, with 70 clinical trials conducted on conditions like Ulcerative Colitis, Hepatitis B, Hepatitis C, and Crohn's disease. CRM wishes to highlight the dedicated efforts of these investigators in this issue. Let's explore and hear their journey filled with experiences into this field.

Dr James Emmanuel
Gastroenterologist & Hepatologist

Queen Elizabeth Hospital

Areas of Interest in Research

Advanced pancreatobiliary and third space endoscopy

My journey in medicine began at Melaka Manipal Medical College (MMMC) for my undergraduate studies. I completed my housemanship training at KL General Hospital in 2011. In March 2023, I obtained my membership in the Royal College of Physicians (MRCP UK) and completed my Gastroenterology and Hepatology Fellowship Training Programme in August 2022. During this transformative period, I had the privilege of a fellowship stint at the prestigious Humanitas Research Hospital in Milan, Italy.

As an investigator, I prioritise trials with real-world benefits for patients. I achieved significant milestones by passing the USMLE examination and the European Specialty Examination in Gastroenterology and Hepatology (ESEGH) in 2020. I serve as a reviewer for esteemed journals like the American Journal of Gastroenterology (AJG), PLOS One, and World Journal of Gastroenterology.

I draw inspiration from local stalwarts in Gastroenterology, Datuk Dr. Ryan Ponnudurai and Dato' Dr. Mahendra Raj, whose dedication to advancing training in Malaysia serves as a guiding light for my professional journey.

Dr James's Research Snapshot

Principal Investigator	1 Study
Sub-Investigator	11 Studies
Abstract Presentation	30 Presentations
Publications	22 Publications

Dr Norasiah Abu Bakar
Consultant Physician and
Gastroenterologist & Hepatologist

Raja Perempuan Zainab II Hospital

Areas of Interest in Research

IBD, Erosive Esophagitis & Chronic Hepatitis C

I was born in Besut, Terengganu. Since 2009, I've worked as a Physician, later specialising as a Gastroenterologist & Hepatologist at Hospital Raja Perempuan Zainab II. I graduated with my MD in July 1999 and completed my Masters in Medicine (M.Med) Internal Medicine in August 2009, both from University Science Malaysia (USM). Currently, I hold positions as Head of the Endoscopy Unit and Gastroenterology Unit.

Following my gazettement as a physician, I pursued further training in Gastroenterology and Hepatology through the Ministry of Health Training Programme from 2011 to 2014. I've actively participated in clinical trials since 2013 and received the Platinum Award for the "Highest Number of Industry Sponsored Research in Year 2017/2018".

Additionally, I contribute to developing Clinical Practice Guidelines (CPGs) for various areas including Chronic Hepatitis C management in Adults, Management of Inflammatory Bowel Disease (IBD), Iron Deficiency Anaemia, and Patient Blood Management. I am also committed to educating future medical professionals, serving as a tutor for medical students and an Honorary Lecturer at Lincoln University and MSU University.

Dr Syuhada Dan Adnan
Consultant Hepatologist

Sultanah Nur Zahirah Hospital

Areas of Interest in Research

Hepatocellular carcinoma, Chronic Hepatitis B, Chronic Hepatitis C and other chronic liver diseases

I am currently the Head of Unit for Hepatology & Gastroenterology in Hospital Sultanah Nur Zahirah and a visiting lecturer for UNISZA. I was a committee member for Clinical Practice Guidelines: Management of Chronic Hepatitis B in adults and was selected as a British Medical Journay (BMJ) Case Report Reviewer in 2020. I started my career as a House Officer in Leicester Royal Infirmary United Kingdom after graduating from Leicester-Warwick Medical School, UK in 2006.

Later, I completed my MRCP UK programme and was subsequently qualified as a physician in 2013. In 2022, I obtained the Fellowship from the Royal College of Physician London and also Edinburgh. In 2015, I joined as a subspecialist trainee in the field of Hepatology and was attached to Selayang Hospital where my research journey really started. I learned a lot about clinical research under the guidance of Dr Tan SS and Dr Haniza Omar.

For me as an investigator, the most significant accomplishment is when the patients achieve a cure from their chronic disease. I always believe the need to do more research in clinical areas in order for patients to have better treatment options.

Dr Azlida Bt Che' Aun
Gastroenterologist, Medical Outpatient Department (MOPD)

Tengku Ampuan Afzan Hospital

Areas of Interest in Research

Gastroenterology, specifically in Hepatitis B, Hepatitis C, Ulcerative Colitis and Crohn's Disease.

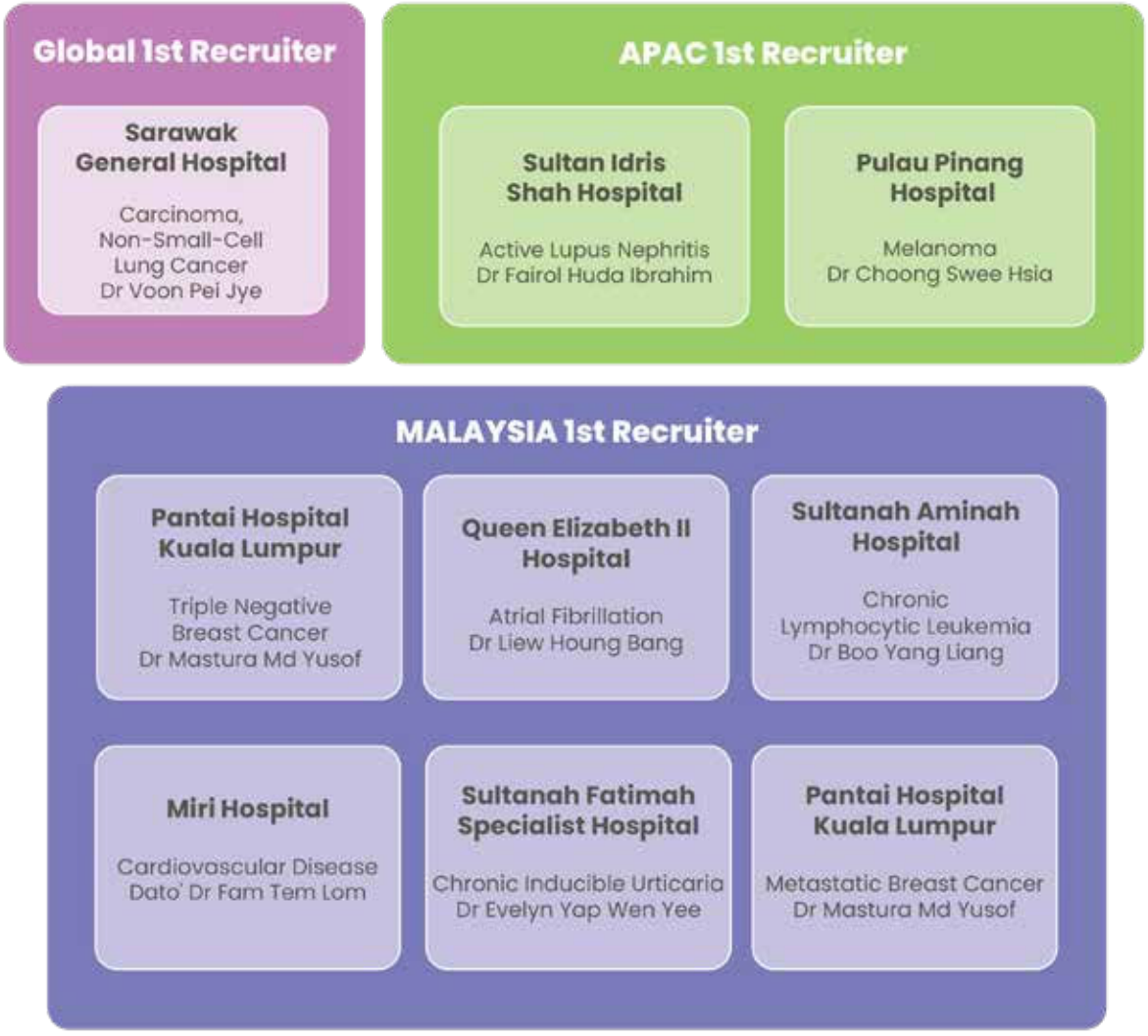
I obtained my MD from the University of Science Malaysia (USM) in 1998 and began practicing medicine in 1999. Subsequently, I completed my Master's in Medicine (Internal Medicine) at USM in 2008 and underwent sub-speciality training in Gastroenterology under the Ministry of Health Malaysia in 2016.

Currently, I serve as the Pahang State Gastroenterologist, primarily based at Tengku Ampuan Afzan Hospital in Kuantan. Additionally, I provide gastroenterology services at Hospital Sultan Haji Ahmad Shah, attend referrals from other district hospitals, Klinik Kesihatan in Pahang, and Darul Makmur Medical Centre.

Since 2012, I have actively participated in clinical research, being involved in over 15 clinical trials to date, with 13 of them as the Principal Investigator (PI). My interest in clinical research sparked during my initial involvement as a sub-Investigator, collaborating with esteemed investigators such as Dr. Tee Hoi Poh and Prof. Dr. Nik Nurfatnoon. I find great satisfaction in providing patients with access to new treatments through clinical trials.

> "For me as an investigator, the most significant accomplishment is when the patients achieve a cure from their chronic disease. I always believe the need to do more research in clinical areas in order for patients to have better options"
>
> Dr Syuhada Dan Adnan

Recruitment Achievements in Sponsored Research 2024



ROADMAP TO BECOMING AN INVESTIGATOR

01 Specialist

Are you a specialist in your area of expertise?

Often consultants or specialists who are sought for to conduct clinical trials.

02 GCP

QUALIFICATION

Undergo Good Clinical Practice (GCP) training and pass the GCP examination.

Usually organised by CRCs at MOH hospitals and by universities.

03 Register

Register your interest to be an investigator with the hospital CRC and CRM.

Approval and support from your department are especially important in your journey to being an investigator.

04 Study Team

PARTICIPATE

Join existing or new study teams as a sub-investigator under the supervision of of the PI to gain needed experience in conducting clinical trial.

05 Perform

EXPERIENCE

Be a valued member in study teams. Perform your role as delegated by PI and always ensure standards of GCP are adhered to.

06 Feasibility

Experienced investigator will be approached by CRM for new feasibility studies.

Questionnaires provided would need to be answered accurately within the timeline agreed.

07 Evaluation

Sponsor or Contract Research Organization (CRO) will approach site & investigator for further evaluation if post-feasibility assesment is successful

08 PI

START UP

Awarded as Principal Investigator (PI) for site or study if selected.

CRM will facilitate PI for study budget and Clinical Trial Agreement review during study start-up.

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

FEATURED SITE

Hospital Sultanah Aminah, Johor Bharu

Hospital Sultanah Aminah, situated in Johor Bahru, is the oldest and most modern medical institution in Johor. It was constructed in 1938 to address community health challenges amid Johor Bahru's rapid development, the hospital initially operated as General Hospital Johor Bahru. It was renamed in 1984 after the mother of then Johor's Sultan, it boasts a main building with five floors and 857 beds, featuring two "T"-shaped wings with 80 beds each. There are departments like Administration, Finance, and Services play integral roles in patient care. Today, as Johor's referral hospital, it offers twenty-one clinical services, nine clinical support services, and five non-clinical support services, with a bed capacity of 1,206 units. Beyond medical care, it has significantly contributed to healthcare personnel development nationwide. With a rich history and a commitment to continuous improvement, Hospital Sultanah Aminah stands as a beacon of quality healthcare in the community.

HSA FACILITIES

- Colonoscopy
- Endoscopic ultrasound (EUS)
- Oesophagogastroduodenoscopy (OGDS)
- CT scan
- Accredited local laboratory
- Echocardiogram
- Invasive Cardiovascular Laboratory (ICL)
- Bone Marrow Transplant
- Daycare Unit

MAIN CLINICAL SERVICES

Surgical Services

- General Surgery
- Plastic and Reconstructive Surgery
- Cardiothoracic
- Orthopaedic
- Emergency and Trauma
- Oral Maxillofacial
- Dental Paediatric
- Otorhinolaryngology
- Anaesthesiology & Intensive Care
- Urology
- Neurosurgery
- Ophthalmology

Medical Services

- Cardiology
- Dermatology
- Respiratory
- General Medicine & Nephrology
- Psychiatry & Mental Health
- Paediatrics
- Obstetrics & Gynaecology

MAIN CLINICAL SERVICES

Clinical Support

- Radiology
- Pathology
- Transfusion Medicine
- Rehabilitation Medicine
- Nuclear Medicine
- Pharmacy
- Dietetics & Food
- Jabatan Kerja Sosial Perubatan
- Medical Record
- Infection Control
- Casemix
- Medico-legal
- Cluster Hospital
- Unit Pesakit Bayar Penuh
- Forensic Medicine
- Clinical Research Centre
- Jabatan Pendidikan Penyakit
- Unit Penyeliaan Penolong Pegawai Perubatan
- Unit Kawal Selia
- Quality
- Occupational Health and Environmental Health
- Unit Perkhidmatan Steril Berpusat (CSSU)
- Unit Perolehan Organ

HSA TEAM

1,010 Total number of doctors

195 Pharmacists

1,561 Nurses

1,206 Beds

1,778 Supportting Staff

1.7m Population Served

source: mycensus.gov.my

HOSPITAL'S SPECIALTIES BASED ON THERAPEUTIC AREAS

- Haematology
- Cardiology

HOSPITAL'S SURGICAL BASED AREA

- Urology
- Neurosurgery
- Paediatric Surgery
- Upper GI Surgery
- Hepatobiliary Surgery
- Colorectal Surgery

CLINICAL RESEARCH CENTRE AT HSA

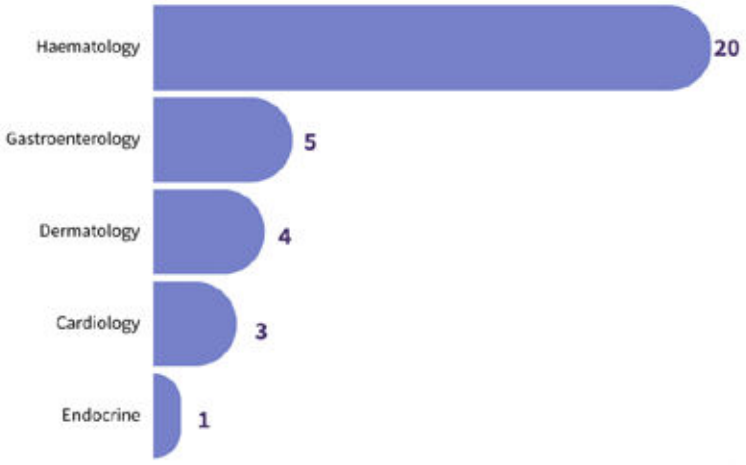
The Clinical Research Centre (CRC) in Hospital Sultanah Aminah Johor Bahru (HSAJB) was established in 2007 within the network of CRCs in the Ministry of Health Malaysia. The CRC in HSAJB primarily functions to support and build research capacity among healthcare professionals within the state of Johor. In its duties, the CRC strives to promote the conduct of high-quality and ethically responsible research that matters to patients in Hospital Sultanah Aminah.

From time to time, the CRC in HSAJB organises professional development courses and assists clinicians in the conduct of their clinical research projects. They also provide guidance to new investigators and researchers on study design, methodology, protocol writing, manuscript preparation, and statistical consultation.

SNAPSHOT OF SPONSORED CLINICAL RESEARCH ACTIVITIES IN HSA (2017 - 2024)

Awarded	63
On-going	33
Start-up	14
Closed/Completed	16

ISR BY THERAPEUTIC AREAS



ACCOMPLISHMENTS IN CLINICAL RESEARCH

Year	Accomplishment
2023	First patient randomized in Malaysia for ANTHEM-UC (Colitis)
	First patient randomized in Global for 1368-0120 study (GPP)
	First patient randomized in Asia for CVAY736O12301 study (Warm AIHA)
	First patient randomized in Malaysia for NS-018-201 study (Myelofibrosis)
	Malaysia Top Recruiter for GRAVITI study (Crohn Disease)
	Malaysia First Recruiter for MANIFEST-2 (Bone marrow cancer)
	Malaysia Top Recruiter for CABL001A2302 (CML)
	Malaysia Top Recruiter for 1368-0027 (GPP)
2024	First patient randomized in Malaysia for MK1026-008 study (CLL)

MEET OUR TEAM

Nurul Atiqah binti Abdul Rahman

Associate Legal Manager and Personal Data Protection Officer
2-time CRM CEO Award Recipient

About My Role

Legal Executive	2016 - 2018
Senior Legal Executive	2018 -2022
Associate Legal Manager	2022 - Present

As the Associate Legal Manager, my responsibilities encompass reviewing agreements for all MOH hospitals and institutions, including public hospitals and institutions under the National Institutes of Health Malaysia. These agreements include the Confidential Disclosure Agreement or Non-Disclosure Agreement (CDA/NDA), Clinical Trial Agreement, Data Sharing Agreement, Material Transfer Agreement, Professional Service Agreements, and more.

Additionally, I oversee the review of preliminary legal documents such as Memorandums of Understanding. In managing the Legal team, I ensure timely agreement reviews while upholding a standard of quick, reliable, and high-quality service. Emphasising adherence to Good Clinical Practice and relevant laws and regulations, my team and I guarantee that all agreements undergo thorough review. I consistently encourage team members to participate in training sessions to enhance their professional development and maximise their potential.

How do legal aspects impact clinical trials, and how does it impact from both sides?

Parties must ensure finalisation of the Study Budget and Clinical Trial Agreement before the commencement of the Clinical Trial. The Clinical Trial Agreement, which incorporates the Study Budget, delineates the rights and obligations of the Sponsor/CRO, the Institution, and the Principal Investigator. To achieve an equitable Clinical Trial Agreement, rather than one-sided, a comprehensive legal review is imperative. The inclusion of an indemnity clause in clinical trial agreements is vital to safeguard the welfare of study subjects.

How do you manage legal risks and ensure smooth trial operations?

We have a proper risk register in which we identified the risk and the probability of its occurrence, as well as the actions taken to prevent the risk from occurring. Hence, all risks will be properly mitigated. To facilitate smooth trial operations and expedite start-up timelines, we commit to reviewing any Confidential Disclosure Agreement (CDA) received within 24 working hours.

This allows Principal Investigators sufficient time to review the protocol and complete feasibility questionnaires before deciding on study participation. Similarly, for Clinical Trial Agreements (CTA), we guarantee endorsement through our CTA system within 14 calendar days, subject to unanimous agreement on the study budget by all negotiating parties.

What part of your role do you find most challenging?

I find the most challenging aspect to be finalising urgent requests for certain projects, particularly when agreements involve multiple parties and non-MOH sites with their own review processes based on unique institutional policies. However, it is rewarding when I successfully complete the task despite the encountered difficulties.

Any department you mostly liaise with?

I work closely with all departments, but particularly with the Finance team. We have been working so well together because cooperation between the two departments is required as the budget review and the Clinical Trial Agreement review need to be completed concurrently using the CTA system. Departments must ensure that the Clinical Trial Agreement is endorsed within the time frame specified..

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

I always look forward to my morning coffee to get my day started, as well as my supportive colleagues in CRM. Also, my drive towards working hard is to ensure a comfortable living means to my family.

Nor Hafiza Binti Johari

Clinical Operations Manager

4-time CRM CEO Award Recipient

About My Role

Study Coordinator	2012 - 2017
Associate Regional Manager	2017 - 2021
Clinical Operations Manager (COM)	2021 - Present

As a COM, I am responsible for providing leadership, regular supervision and support to my direct reports, the Associate Regional Managers (ARMs) to ensure the smooth running of 5 regions, maintaining compliance with the relevant industry regulations as well as internal policies, achieving the company's objectives and reports directly to the Head of Department (HOD). I work closely with ARMs to identify, recommend, develop, implement, and support the trainings goals for the SCs and develop and maintain good relationship with a wide range of stakeholders (e.g. PI, CRC, Sponsor, CRO) to ensure operations are aligned with organizational objectives.

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

Clinical research offers unique opportunities and advancement in healthcare and makes tangible difference in patients' lives. Witnessing the transformative impact of research firsthand, whether it's pioneering new treatments or improving existing ones, inspires me every day.

Getting new knowledge, and hearing the clinical research opportunities, challenges and requirements from different perspectives or industry teach me indirectly on how to adapt and move forward. Even though my current roles are not involving directly with trial management at the site level but managing the earlier part of the trial such as resource planning, contract and budget negotiations, allow me to refresh my knowledge and skills.

What has been your greatest learning opportunity in clinical research?

One of the greatest learning opportunities I've had in clinical research has been understanding how to effectively manage feedback. Feedback is crucial in this industry as it not only helps us improve our processes but also enhances the quality and integrity of our research outcomes.

The importance of actively seeking feedback is not only from various stakeholders, including colleagues, supervisors, investigators, and site staff. Each perspective offers valuable insights that can uncover blind spots and identify areas for improvement, especially when clinical operations are the biggest team in CRM.

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

My strong value would be to stay resilient and adapt to what I have been assigned to. Clinical research is a field that often presents unexpected challenges, whether they arise from changes in study protocols, unforeseen obstacles in data collection, or shifts in project timelines. In such a dynamic environment, adaptability is essential to navigate through these challenges and making progress towards research goals and at the same time achieving the KPIs for the year.

Adaptability allows me to respond effectively to changes by adjusting strategies, priorities, and approaches as needed. It involves being flexible in mindset and resourceful in problem-solving, enabling me to overcome obstacles and find creative solutions to complex problems. There are times when we need to intervene and discuss with study team, on how to move forward with the recruitment activities, or adhere to the timeline for database lock such as putting resources ensuring the deliverables are on time and with high quality.

What drives you to move forward?

Colleagues play a crucial role in keeping me motivated. Working alongside talented and passionate individuals fosters a sense of camaraderie and teamwork, making the work environment both enjoyable and rewarding. Sharing ideas, problem-solving together, and celebrating successes as a team creates a supportive and inspiring atmosphere. I am truly blessed that my CRM team always support each other even if we are not in the same department.

Additionally, the constant learning and professional development opportunities keep me engaged and motivated. Every day presents new challenges and opportunities to expand my knowledge, develop new skills, and grow personally and professionally. This continuous learning journey keeps me stimulated and excited about the work I do. And of course, not forgetting a cup of coffee for daily booster would help me stay alert and energetic.

PUBLICATION

Comparing the Differences Between Memorandum of Understanding and Memorandum of Agreement

The Current Law Journal [2024] 1 CLJU(A) iv
Authors: Siti Nuralis Abd Muis, Nurul Farzana Mohd Amin & Nurul Atiqah Abd Rahman

A Memorandum of Understanding (MOU) is a legal instrument between two or more parties that outlines a common goal. The MOU and the Memorandum of Agreement (MOA) are frequently confused by laypeople, but they are not the same. An MOU is a preliminary document that indicates the parties' intention to collaborate in general before they can finalise the parties' responsibilities in a formal agreement.

An MOU is not usually a legally binding contract and is unenforceable by law unless the clauses in the MOU state otherwise. It is a crucial step for any prosperous partnership to reach.

On the other hand, MOA is a legal instrument between two or more parties for the purpose of specific collaboration, intended to be legally binding and enforceable by law.

An MOU can reduce the risk of parties entering into an MOA. Because trust has already been established, the parties can anticipate each other's
expectations.[1]

Role of Clinical Research Malaysia ('CRM') in Reviewing MOU For Ministry Of Health ('MOH') Research Sites

Clinical Research Malaysia ('CRM') helps review[2] the MOU for collaborations entered with CRM and if it involves Ministry of Health ('MOH') research sites. CRM will ensure that the review of the MOU complies with all applicable laws and guidelines. CRM will assist in catering to the discussion on the description and scope of the MOU which the parties have agreed on, as well as the agreed-upon roles, responsibilities and contributions of the parties. It is important for parties to negotiate and agree on the terms of the MOU to ensure that the parties' mutual understanding, goals and objectives of the MOU are achieved.

Important Elements for Memorandum of Understanding

Parties to the Memorandum of Understanding and Due Diligence

In the MOU, it is imperative that the company name (along with the company number), the national registration identification number of an individual, and their address all be spelt out in an accurate manner. This part is similar to other agreements in which the parties with legal entities must be identified.

Nevertheless, before entering into a contract with one another, the parties in many cases fail to perform the company search or bankruptcy search that is required of them. The aforementioned search is extremely important, particularly for MOUs entered into with companies based in Malaysia or with individuals from Malaysia. The search is being done as part of risk mitigation because it is appropriate to ensure that CRM is collaborating with operational businesses or an individual who has not declared bankruptcy.

But what about non-Malaysian entities? In this scenario, parties would normally conduct third-party due diligence activities. The purpose of conducting third-party due diligence is to protect the organisation's reputation, assets, and interests while at the same time lowering any potential risks that may be present. Gathering information about a third party's background, financial stability, legal and compliance history (including anti-bribery and anti-corruption), business practices, and overall reputation is required by the due diligence guidelines for third parties. It is worth noting that due diligence activities are essential for new companies dealing with CRM. However, the re-assessment shall be done yearly or annually or as the company deems fit.

Purpose of the Memorandum of Understanding

An MOU will always include a clause specifying the objective of the relationship governed by the said legal instrument. It should provide an explanation as to the motivation behind the creation of the MOU. It details how one party will benefit from the collaboration between the other party. The overall intention of the parties is to be laid out to ensure that the parties do not have any intentions that have not been disclosed to one another, which may result in a dispute in the future.

Duties and Responsibilities

This is another essential section of the MOU in which the parties' obligations and responsibilities are spelt out. It is always preferable for the responsibilities and obligations of each party to be listed separately. Additionally, shared responsibilities should be specified. This part must be written with clarity and is often the longest section of the MOU.

Formalisation of Proposed Collaboration

It is advisable for parties to ensure that any proposed collaboration between them will be formalised by a separate written agreement outlining the parties' rights and responsibilities, including any financial obligations.

Any such collaboration shall commence and can only be implemented after the parties' duly authorised representatives have signed the aforementioned written agreement.

Duration, Revision of the Memorandum of Understanding

Once parties have signed an MOU, its duration is typically not perpetual but rather limited to a specific time frame. In the event that a definitive agreement is not reached during the duration of the MOU, the parties would typically revisit and discuss whether it is necessary to renew the MOU after conducting a review to monitor the outcome of the MOU.

Dispute Resolution

As mentioned earlier in the introduction, in contrast to standard contracts, an MOU is not legally enforceable unless the parties expressly provide for it in the document. As a result, a formal method for resolving disputes, such as arbitration and litigation, is typically avoided in the context of an MOU. When conflicts arise, the parties involved should agree that they will resolve the conflict in good faith or amicably through mutual negotiations. In the event that the disagreements are not resolved after the allotted amount of time, they should be brought to the attention of higher officials within the organisation that the parties represent. In any event, if the disagreement is not resolved, the parties may reach an agreement on an alternative method for resolving the disagreements than those specified in this clause should the need arise.

Intellectual Property

As for the intellectual property clause, it is typical for it to be as general as possible in the MOU, stating that the background intellectual property shall unquestionably belong to the owner. Any new inventions resulting from the intellectual property must be disclosed. They belong to the parties if invented jointly and the sole inventor if solely invented. Any percentage or share of intellectual property created as a result of the project or the collaboration will be specified in a separate definitive agreement.

Situations that make MOU a Legally Binding Contract

It is significant to understand that MOU usually contains the "subject to contract" clause, as spelt out in Charles Grenier Sdn Bhd v. Lau Wing Hong [1997] 1 CLJ 625. In this case, as the judge explained, the preliminary agreement contains such a clause to symbolise the ongoing negotiation between the parties and they are not intended to be bound by it until a formal and definitive agreement is formed. However, further argument was found in Ayer Hitam Tin Dredging Malaysia Bhd v. Y C Chin Enterprises Sdn Bhd [1994] 3 CLJ 133 as the court stated that a "subject to contract" clause does not stop establishing a binding contract.

Further, it is crucial to note that for a preliminary agreement to be legally binding, the elements of certainty of the terms and "meeting of the minds" of the parties must be established before the court as explained in Syarikat Pertanian Emmal Sdn Bhd v. Tractors Malaysia [1982] Sdn Bhd [2009] 10 CLJ 714. Further application of this concept can be found in AHT Properties Sdn Bhd & Ors v. Tan Yee Hee & Ors [2010] MLJU 1957, where the judge held that a confirmation letter is a legally binding agreement due to the certainty of the terms. In the confirmation letter, the parties spelt out the essential terms for the sale and purchase of shares, as the price and terms of sale have been stated. Furthermore, the fact that one of the shareholders acted upon the terms of the confirmation letter symbolised the intention of the parties to treat the confirmation letter as a valid and legally binding agreement.

Another notable discovery is a 1997 case, Lim Hong Liang & Anor v. Tan Kim Lan & Anor [1997] 4 CLJ 175. It was contended that the parties' MOU were legally binding, and Tan Kim Lan had breached the said MOU when he entered negotiations with third parties. The plaintiff's stance was that the MOU contained clauses on time is of the essence and governing law. The court was of the view that even when the MOU contained such clauses, the fact that the MOU did not have finalised and expressed terms, altogether with various approvals still needed to be obtained clearly showed the parties' intention not to treat the MOU as a legally binding agreement. The court held that the MOU was insufficient to be considered a valid and binding contract.[3]

By applying all these legal authorities, the MOU can be a legally binding contract if the parties intend to do so by "meeting of the minds" when negotiating and agreeing to the terms of the MOU. This can happen when the parties have a mutual understanding of the MOU's legality and if any performance could demonstrate the intention to make the MOU a legally binding contract. Moreover, there is a solid reason why the common practice of drafting an MOU is to make it as vague and wide as possible, especially because specific, clear and express terms of the MOU can contribute to the validity of the MOU and form a legally binding contract. The parties to an MOU must take note of this when entering an MOU to ensure that the parties are aware of the legal obligations that arise from the MOU.

Salient Points Why MOA is a Legally Binding Contract and not MOU

The rule of thumb for an MOA to be a legally binding contract is the structure of the MOA itself, which is similar to a contract. For a contract, the general elements are: i) offer, where a party make a promise for an action; ii) acceptance, when the offer is accepted ambiguously by the other party; iii) consideration, which refers to something of value promised in exchange for the action and; iv) consent, where the contracting parties have the "meeting of the minds" of the basic substance and terms of the contract. These four elements are also applicable to MOA. In an MOA, the parties usually clearly spell out the obligations and commitments as well as the allocation and management of its risks. Further, it provides express manifestation that the parties are bound by its terms and strict compliance with it, in addition to the statement of intention to form a legally binding contract between the parties. In terms of the language of law, MOAs generally adapt similar linguistic features as contracts, making them obligatory in nature.

Important Elements for Memorandum of Understanding

In conclusion, an MOU is important as it establishes the mutual objectives and intentions of the parties prior to entering into a fully binding formal agreement and further serves as an instrument to ease, facilitate and allow a smooth working relationship and partnership between the organisation and parties. Meanwhile, an MOA is a formal agreement that details the obligations and commitments of the parties and is legally binding.

References

1. Sapna Goundan, 'Memorandum of Understanding Vs Contract: What's The Difference?', Sprint Law (Web Page, February 2022) <https://sprintlaw.com.au/ articles/mou-vs-contract/>.
2. Currently, MOUs are reviewed by the CRM Legal Department without any legal review charges. Once all the parties have negotiated and agreed to the terms and conditions in the MOU, CRM will coordinate the signatory process with the relevant parties. This may involve a signing ceremony, electronic signature or another method mutually agreed upon by the parties.
3. Cassandra Thomazios and Celinne Teh, 'Do I Have A Contract? Preliminary Agreements in Acquisitions', Mah Weng Kwai & Associates (Web Page, October 2020) <https://mahwengkwai.com/ do-i-have- a-contract-preliminary- agreements-in-acquisitions/#:~:text=The%20general%20rule%20is%20that,1996%5D%203%20MLJ% 20327>.

CRM IN PHOTOS

Meeting with Dr. Hualong Sun, the Chief Strategy Officer of the China Clinical Service Center.

11 Jan

Meeting with Disruptive Doctors

18 Jan

Visit by Centre for Clinical & Translation Research, Kyushu University, Japan.

19 Jan

Engagement with the delegation from Cheras Rehabilitation Hospital led by its Director, Dr Faizul Nizam.

29 Jan

CRM together with Datuk Seri Dr Dzulkefly Ahmad met with Dr Hytham Al-Masri, President and CEO of Hematogenix.

6 Feb

Engagement with Prof Wang Zhe, from Guangdong TCM Hospital, Founder & CEO of Tilcure Biotherapeutics. Together with Dr Low Ley Hian, Biogenes Technologies Global Alliance Lead.

7 Feb

Meeting with Mr. Uno Wao, First Secretary, Health, Labour & Welfare Attache, Embassy of Japan in Malaysia.

23 Feb

Connecting with Director of R&D of DNDi, Dr. Laurent Fraisse, discussing on CRM's role in facilitating sponsored clinical research industry.

5 Mar

Meeting with Novo Nordisk Pharma Malaysia and Dubai.

19 Mar

Meeting with Zuelling Pharma's COO Ms Yvonne Cheah

25 Mar

Met with Ms Melissa Sun, CEO of Yaoyanshe, provider of clinical research innovative platform.

25 Mar

Touchbase meet with AstraZeneca team

25 Mar

CRM IN PHOTOS

Meeting up with Taiho Pharmaceutical.

26 Mar

Meet with Dr Terttu Harring, President, Sites & Patients, and Serena Chan, Head of APAC Clinical Operations, Syneos Health.

29 Mar

Meet with the National Cancer Society Malaysia, Dr. Murallitharan, Director of NCSM, Dr. Kavinash, Research Coordinator, Dr. Jason, Operations lead and the team

5 Apr

Meeting with Dr Yap Wei Aun, CEO of Health Transformation Office

5 Apr

Meeting with Prof Juliana Chan and Dr Benny Kok from The Chinese University of Hong Kong (CUHK)

22 Apr

Meet with Health Advisor and Science & Innovation Officer of British High Commission.

30 Apr

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