By Clinical Research Malaysia

CRM bulletin

of Clinical Research and Therapy

ISSUE 15

Celebrating Clinical Trials

Malaysian Style

RESEARCH PERSONALITY
Dr Toh Teck Hock

SPECIAL COVERAGE
MoU Signing with FIND

FEATURED SITE
Hospital Sultanah Bahiyah

ABOUT CLINICAL RESEARCH MALAYSIA

Clinical Research Malaysia (CRM) exists to advance global health solutions for a brighter, more hopeful future for the people by providing speedy and reliable end-to-end clinical research support for quality studies. As these studies unfold, we work together with our partners to create an impetus in delivering better treatment to our end consumers, while at the same time creating high-skilled job opportunities.

The strength of our operation lies in our innate understanding of the local clinical research landscape and implementation of international standards. This, when considered in parallel to the fundamental backing of the government ministries, provides us with an incomparable advantage, as we work hand-in-hand with our partners from the nascent stages of development to materialisation of the end product.

In the journey towards a brighter and better future, we facilitate the entry of industry-sponsored research into Malaysia, working closely with the government and relevant authorities to ensure that all regulations and best practices are met.

In CRM, we credit the outstanding performance to the team we have anchored from within our organisation. Their endless pursuit of innovation and continuous improvement have propelled CRM forward to optimise the opportunities that come our way. In tandem with our passion for the clinical research landscape, we ensure core values of transparency, honesty, accountability and trustworthiness resonate throughout CRM. These qualities are also cascaded to our principal investigators and Study Coordinators, who act as the catalysts of the clinical research process.

As CRM vouches for an aspiring future in the clinical research industry, we have implemented mechanisms to expand hospital capacity for clinical trials and tests. This is possible by tapping into our vast talent pool consisting of principal investigators and medical assistants.

CRM
CLINICAL RESEARCH MALAYSIA
Your Global Solutions in One Nation

Contents

FROM THE CEO's DESK

It is always an exciting time as we progress into the third quarter of each year because it is during this phase that we can see most of our efforts blossom into something of significance. At this juncture also, I would like to take this opportunity to highlight the fantastic achievements of our doctors in driving more high-quality clinical trials here in Malaysia. In recognising their contributions, we have held our annual Clinical Trials Day where we awarded them with the CRM Industry Sponsored Research Award – an award given to high achievers in clinical trials in Malaysia. We hope that with such awards, more people will step up their game in their respective fields.

As CRM is growing at a rapid pace, we recognise the importance of forging partnerships with global entities that are paving the way for better healthcare. To begin with, we have the National University Hospital Singapore (NUHS) team visiting the Director-General of Health, Datuk Dr. Noor Hisham in Malaysia. NUHS has also shown a strong interest to collaborate with Malaysia in clinical research and training. With this, we have reached another important milestone in our Phase 1 Realization Project. Next – with amazing help from our South Korean counterpart, C&R Research Inc. – the CRM team together with Datuk Dr. Noor Hisham went for a series of business networking meetings in Seoul. During the visit, we took the opportunity to promote Malaysia's clinical research capabilities to the pharmaceutical companies in Korea in a bid to encourage them to conduct clinical trials here in Malaysia. I truly believe that by building trust with our current partners and expanding trust to our future partners, we will be able to position Malaysia as the site for sponsored research in this region.

As our faithful readers might know, one of our aims at CRM is to become a truly global research organisation. In line with our core values of Transparency, Honesty, Accountability & Trustworthiness, we strive to achieve the highest standards in the way we conduct our business. As such, we are currently at the final phases of obtaining the ISO 9001:2015 accreditation, which we work very hard to obtain since last year. Being accredited with ISO 9001: 2015 will demonstrate the quality of management we are practicing within CRM and the consistent standard quality of clinical trials that are being conducted at all sites in Malaysia. We hope to achieve and obtain this accreditation by early 2019.

Finally, I would like to also take this opportunity to thank all of our people in CRM for striving hard in making the organisation a strong force it is today. For our readers, I hope you will enjoy reading this bulletin and will gain more insight on what we do, the kind of activities we conduct and most importantly, appreciate the efforts the whole community is putting in to make our world a better place to live in.

Bringing Malaysia to Boston at DIA 2018 Annual Meeting

Boston, 24 – 28 June 2018 – Clinical Research Malaysia was present at the DIA Annual Conference in Boston to highlight to the international audience on Malaysia's capability and achievements in industry-sponsored research. Besides exhibiting at the booth, the team at CRM had the opportunity to visit Novartis Institute of Biomedical Research and were updated on some of the innovations that are going on at Novartis. The team also visited Karyopharm Therapeutics Inc. headquarters in Newton, MA, and met with their amazing leadership team led by Sharon.

Nurturing New Talents in ISR: Endocrinology

PUTRAJAYA, 25 July 2018 – A Talk Series on Nurturing New Talents in Industry Sponsored Research focusing on endocrinology was held at Hospital Putrajaya with the aim to develop and grow the pool of investigators in clinical research. The half-day event was well attended by over 30 participants comprising of doctors and nurses. Among the topics covered include the basics of clinical research, best practices and expectations towards investigators in clinical trials. Dr. Zanariah Hussein (Heald of Medical Department, Hospital Putrajaya) and Dr. Shweta Uppal (Head of Clinical, Medical, Regulatory and Quality at Novo Nordisk) were among the speakers on that day.

Connecting with the Koreans in Digital Health

SEOUL, 29 July-1 August 2018 – The Director-General of Health Malaysia, Datuk Dr. Noor Hisham Abdullah and the CRM team had a series of business networking meetings with the local Korean sponsors and Korean Government Agencies in Seoul, Korea. Meetings were also held with the Korean Healthcare Industry Development Institute (KHIDI), KoreaBio, Bioinfra Life Science, JK Medical Group, GeneOne Life Science, SK Chemical and Genexine. These meetings were made possible by CRM's counterpart, C&R Research Inc., a leading contract research organization in South Korea. The Koreans exhibited and demonstrated various digital health innovations that will change the future of healthcare in significant ways. Through these meetings, CRM promoted Malaysia's clinical research capabilities and encouraged Korean pharmaceutical companies to conduct clinical trials in Malaysia.

Dr. Albiruni Razak speaks at CRM's Special Series Talk on Phase 1 Clinical Trials

KUALA LUMPUR, 15 August 2018 – CRM was honoured to have Dr. Albiruni Razak to speak at its Nurturing New Talents in ISR talk. Dr. Albiruni shared his experience as a Principal Investigator in various Phase 1 clinical trials at the Princess Margaret Cancer Centre, Toronto, Canada. About 40 participants from various public and private hospitals as well as clinical research industry players were present to meet the Malaysian-born doctor who created a name for himself at the global clinical research stage.

Dr. Abdul Razak is an Assistant Professor at the University of Toronto. Clinically, he is a Staff Medical Oncologist in Phase 1 Clinical Trials and Sarcoma at the Princess Margaret Cancer Centre and Mount Sinai Hospital, Toronto. He also leads the Medical Oncology Sarcoma Program at both institutions. Originally from Malaysia, he underwent medical and oncology training in Ireland, England as well as Canada. He was the recipient several international awards, to include the Young Investigator Award from the American Society of Clinical Oncology (ASCO), Merit Award from the Conquer Cancer Foundation as well as the Mick Knighton Mesothelioma Award from the British Lung Foundation. Dr Abdul Razak was also the inaugural recipient of the Sarcoma Cancer Foundation of Canada Fellowship. Dr Razak's main interest is new drug development, especially in the field of sarcoma. He has authored over 80 papers, including in high impact journals such as Journal of Clinical Oncology, Cancer Discovery, Clinical Cancer Research and Cancer.

Another Milestone in the Phase 1 Realization Project

KUALA LUMPUR, 16 August 2018 – The National University Hospital (NUH) Singapore Oncology Trials team comprised of Prof. Dr. Goh Boon Cher, Prof. Dr. Lee Soo Chin, Dr. Stephanie Tan and Joanne Chio gave a courtesy visit to the Director-General of Health, Datuk Dr. Noor Hisham at his office. They also visited active oncology clinical trials sites which include Hospital Ampang, the National Cancer Institute (IKN) and Sarawak General Hospital. NUHS extended their fellowship programme to train Malaysian investigators in Phase 1and have shown interest to collaborate with Malaysia in clinical trial projects, lab work and other healthcare initiatives. This could be the start in the change of paradigm from being 'competitors' to 'collaborators' between the two neighbouring countries.

Celebrating Clinical Research Through the Clinical Trials Day 2018 & 2nd IKN Research Day

PUTRAJAYA, 5 September 2018 – Clinical Trials Day 2018 was held at the Institut Kanser Negara (IKN), its second time since its initiation last year, to celebrate patients, volunteers and medical professionals involved in clinical trials. Clinical Research Malaysia (CRM) partnered with Clinical Research Centre (CRC) and IKN to organise this momentous event in conjunction of IKN's 5th anniversary.

This event was well attended by all stakeholders in the clinical research industry. Various talks by prominent research personalities and patient support talks were organised for the general public as well as for the medical personnel to raise awareness on the importance of clinical trials.

At the event, a CRM Industry Sponsored Research Award was given to high achievers in clinical trials here in Malaysia to recognize their contribution in industry sponsored research, as well as to spur and encourage more of such efforts. IQVIA™ Malaysia received the CRO of the Year Award for highest number clinical trials with trial site activation & recruitment number for the year 2017, Dr Shereen Ch'ng Suyin (Hospital Selayang) and Dr Wong Yoke Fui (IKN) received the Top Recruiter Award for consistent performance in patient recruitment for clinical trials initiated in Malaysia for year 2017, Dr Voon Pei Jye (Sarawak General Hospital) received the Investigator of the Year Award for outstanding achievement as principal investigator in clinical trials for year 2017 and Institut Kanser Negara received the Clinical Trial Site of the Year Award for outstanding achievement in being among the top oncology trial site in Malaysia for year 2017.

The event was officiated by the Deputy Director-General of Health (Research & Technical Support), YBhg. Datuk Dr. Shahnaz Murad. Also present was the Director of Institut Kanser Negara, YBrs. Dr. Asmayani, CEO of CRM, Dr. Akhmal Yusof & the Deputy Director of CRC National, YBrs. Dr. Kalairasu Periasamy.

Malaysia's Site Achievements

Several Ministry of Health sites in Malaysia have achieved recognition from the Sponsors due to their achievements in patient recruitment. Below are the sites and principal investigators (PI) involved in the study:

TOP RECRUITER

GLOBAL FIRST RECRUITER

MALAYSIA FIRST RECRUITER

Dr Toh Teck Hock

Paediatrician and Head of Clinical Research Centre, Sibu Hospital

Before I joined Sibu Hospital, I have worked in the United Kingdom, Singapore and Australia for a number of years as a paediatric trainee. Besides general paediatrics, I also work in the areas of developmental paediatrics and community child health. I am an Adjunct Professor for SEGi University Medical School as well as the Special Olympics Asia Pacific Regional Clinical Advisor in Health Promotion®, Vice President for the National Early Childhood Intervention Council, Council Member for Sarawak State Council for Early Childhood Education and Development, National Assessor for the Baby-Friendly Hospital Initiative and Secretary of the Association for Children with Special Needs Sibu. Besides scientific papers, I have also published parent-teacher handbooks on ADHD, language development and breastfeeding, as well as children reading / colouring books, and books on Chinese literary prose / short stories. I received The Outstanding Young Malaysian Award in 2010, and Special Education Network in Asia Advocacy Award in 2018.

Can you tell us when and how did you first got involved in clinical research?

I was a Houseman working in West Cumberland Hospital, Whitehaven, United Kingdom. It was during a post-call ward round with my Consultant Surgeon, where he questioned the usefulness of doing an abdominal x-ray on patients presented to A&E with abdominal pain. I then took up the challenge to help finding an answer to this research question. I spent the following two weeks in the medical record office, reviewing case records. Thinking back, the "study" could have been done a lot better. However, I was proud because I remember I was the only Houseman then given the opportunity to present my finding in the hospital grand round; and the hospital subsequently reviewed the guideline on abdominal x rays.

How has a clinical trial changed your practice and management of patient care?

There are many variations in clinical practice, and with the experience, I have certainly improved my clinical skills over the years. However, it is the knowledge and skills acquired during the training and doing of clinical research that taught me to be evidence-based, doing no harm, balancing the risk and benefits when I manage a patient. Being involved in the clinical research, I also gain the ability to appraise research finding more accurately (often that means, to "reject" the so-called "evidence"), and to apply that in general patient care. Other types of research are useful in clinical practice too. For example, good epidemiological and surveillance studies provide the clinicians solid data on current and real problems that are faced locally (hence, not just "textbook says"). Health system research and behavioural studies, although not having direct impacts on individual patients, they provide us good value in overall patients care in the hospital and clinics by improving our policies.

You were recently announced as the Top Recruiter for a paediatric study (RESPIRE). Can you share with us what it takes to ensure successful recruitment of a clinical trial?

It was a "difficult" in patient study, because of short recruitment window period, meaning to say the study team often have to recruit and perform study procedure outside of office hours, till midnights. Doing study procedures (on top of routine care provided) on these young infants have extra challenges – we often had to rethink the risks and benefits of doing study on these young infants at the bedside.

However, a good team is the crucial successful factor for this kind of study. People involved include the co-investigators, study coordinators, research pharmacists and the CRO, as well as those in the office and colleagues who co-manage the children in the wards. I define "good" as someone who shares the common goal (i.e. to complete the study safely), committed, and passionate about doing a study.

What is your motivation behind conducting clinical trials?

It is the curiosity about "why?" and "can things be done better?" that always keep the clinicians moving forward, because we always have more patients that will come to us with the same problems. Of course, to be part of the world leading clinicians that contribute towards advanced healthcare make all of us proud.

What one word best describes your career as a clinical researcher / investigator? Why?

Colourful. No single study is the same, and no single patient is the same. There is always excitement when a study starts, comes to the closure and when the results are revealed. There is plenty of opportunities to meet a variety of people during training, presentation and scientific meetings. Coaching the juniors are always as fun as learning from the senior. That makes life as a clinician more colourful. It is not just the routine of seeing patients in the clinic and doing ward round day in day out until one retires.

In the field of clinical research, where do you wish to see Malaysia in the next 10 years?

More clinical researchers / study teams that can conduct clinical trials that can make a significant change in patient / healthcare globally. With this, there shall be more trials conducted safely, and with quality. It requires our country laying down infrastructure, policy, environment and resources to achieve this.

What changes would you like to see being made by the policy makers to create a more conducive ecosystem for the conduct of clinical trials in Malaysia?

Better distribution of resources (human and funding). At the moment, there are hospitals / centres with little manpower (and resources), overloaded works but keen clinicians / researchers. Unfortunately, the reverse is also true, which lead to an inefficient system (and sometime wastage). The good clinicians / researchers need to be recognised and given better resources and support, not only to conduct clinical trials, but to guide the juniors. It is tomorrow's clinicians / researchers that make a country successful.

CRM in Photos

I AM AWARE Roadshow in Klinik Kesihatan Seberang Jaya, 7 May

CRM Masterclass in Cardiology, 15 May

Aurigene (India) Visit, 22 May

Visit to PAREXEL Global HQ in Boston, 26 June

DIA Annual Meeting in Boston, 24 - 28 June

CRC Network Meeting, 10 July

Meeting with School of Pharmacy, IMU 24 July

Nurturing New Talents in Industry Sponsored Research - Endocrinology, 25 July

Visit to the Healthcare Innoseum by KHIDI, 30 July

Meeting with GeneOne Life Science Inc., 31 July

Meeting with KoreaBio, 1 August

Meeting with SK Chemicals, 1 August

Nurturing New Talents in ISR - Special Series with Dr. Albiruni Razak, 15 August

Meeting with Minister of Health Malaysia & Cancer Research Malaysia, 15 August

Visit from National University of Singapore Delegates, 16 August

I AM AWARE Roadshow in Klinik Kesihatan Mahmoodiah, 27 August

I AM AWARE Roadshow in Klinik Kesihatan Peringgit, 29 August

Clinical Trials Day 2018 & 2nd IKN Research Day, 5 September

Meeting with Datuk Dr Christina Rundi (Sabah State Health Director), 2 May

I AM AWARE Roadshow in Klinik Kesihatan Greentown, 2 May

Samsung Bioepis (Korea) Visit, 2 May

1st Meeting between SRP, MREC & NPRA for FIH Trials, 24 May

Bachelor of Pharmacy (Hons) students attachment with CRM, 25 May

Meeting with Sin Chew Daily, 30 May

ASM of the Malaysian Society of Gastroenterology & Hepatology 2018, 13 -15 July

1st Borneo Diabetes Conference 2018, 13 - 15 July

Meeting with Hematogenix Laboratory Services, US & Minister of Health Malaysia, 18 July

Meeting with Bioinfra Life Science Inc., 30 July

Courtesy call to the Ambassador of Malaysia to Korea (Republic), 31 July

Meeting with JK Medical Group, 31 July

Visit to Novotech office in Seoul, Korea, 2 August

MoU Signing Ceremony between CRM & FIND, 6 August

meeting with Linda M. Distlerath, Deputy Vice President, PhRMA, 13 August

Royal Embassy of Denmark in Kuala Lumpur visit, 21 August

European Society of Cardiology Congress 2018, 25 - 29 August

4th International Pharmaceutical Research Conference 2018, 25 August

Simultanious Clinical Trials Day Celebratio @ Hospital Queen Elizabeth II, 5 September

Visit to KBioHealth, Korea, 6 September

Asia Bioindustry-leaders network meeting at Bioplus 2018, Seoul, 6 September

MALAYSIA TAKES THE LEAD ON A PUBLIC HEALTH APPROACH TO HEPATITIS C WITH NEW INITIATIVE TO ENHANCE DIAGNOSIS & TREATMENT

- **Foundation for Innovative New Diagnostics (FIND) and Clinical Research Malaysia (CRM) sign Memorandum of Understanding to work together to simplify and decentralise hepatitis C virus (HCV) screening and treatment**
- **Initiative conducted in partnership with the Drugs for Neglected Diseases initiative (DNDi) and in collaboration with the Ministry of Health in Malaysia, underscoring the government's world-leading efforts to tackle the disease**

PUTRAJAYA, 6 August 2018 – The Foundation for Innovative New Diagnostics (FIND) and Clinical Research Malaysia (CRM) today signed a Memorandum of Understanding (MOU) to collaborate in the research and development of an innovative Hep C diagnostic testing strategy.

CRM is a non-profit company owned by the Ministry of Health in Malaysia, and this work underscores the importance of research and development in the government's pioneering efforts to tackle the disease.

The initiative is being conducted in continuation of a partnership with the Drugs for Neglected Diseases initiative (DNDi) and forms part of a larger FIND project known as ***Hepatitis C Elimination through Access to Diagnostics (HEAD-Start)***, supported by Unitaid. Malaysia is the only high-middle-income country included in the project.

> **It is a great honour to be part of this research and development effort with FIND, that will eventually lead to more cost efficient and earlier detection of the Hepatitis C. In line with our effort to be a globally trusted organization and participate in research that matters to the Malaysian population we will continue to strive our best to deliver together with our partner FIND.**
>
> ***Dr. Akhmal Yusof***
> ***Chief Executive Officer of Clinical Research Malaysia***

Although the World Health Organization (WHO) has prequalified different types of HCV tests, screening vulnerable and hard-to-reach populations remains a challenge due to centralized health services, making it difficult to identify those with the disease who need to be linked to care and treatment. FIND will demonstrate the feasibility of using rapid diagnostic tests (RDTs) in decentralized primary healthcare facilities, and provide technical assistance to the Ministry of Health in Malaysia to support the project.

> **The introduction of RDTs and simpler diagnostic pathways is a critical step in scaling up hepatitis C care. This MOU with CRM allows us to work closely with the Malaysian government and ensure that the evidence generated can be used to inform national policy so that more people can know their status and enter the care cascade.**
>
> ***Catharina Boehme***
> ***Chief Executive Officer of FIND***

All patients screened during the study with World Health Organization pre-qualified diagnostic tests and confirmed as having active HCV (viraemia) will be linked to care. Treatment will be provided:

- either as part of an ongoing DNDi clinical trial, which is co-sponsored by the Malaysian Ministry of Health and designed to assess the efficacy and safety of a new, alternative treatment regimen combining sofosbuvir with the investigational drug ravidasvir. Results from the first stage of the trial published in April 2018 show this drug combination to be safe and effective, with extremely high cure rates for patients, including hard-to-treat cases;

Mr. Zachary Katz, Chief Access Officer of FIND showing the Rapid Test Kit while giving his speech.

- or by the Malaysian national HCV programme, which, following an ambitious treatment strategy to overcome the prohibitively high cost of HCV treatment in the country, now offers free hepatitis C treatment (sofosbuvir/daclatasvir) in 21 government hospitals.

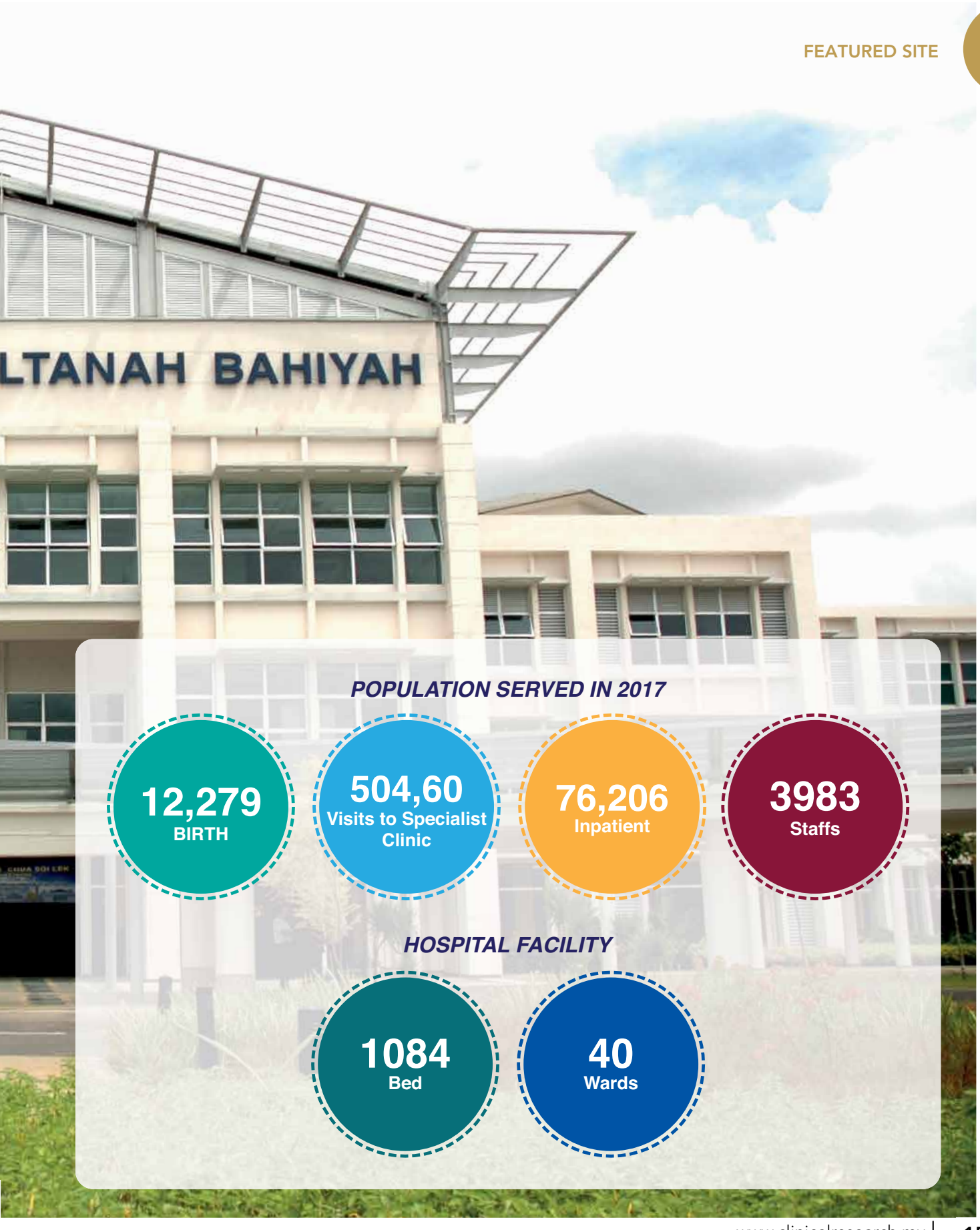
The evidence generated by both projects (screening and subsequently research and development of new innovative diagnostics kits for HCV) will allow the national guidelines for the management of hepatitis C to be more empowered backed by evidence-based medicine. The national guidelines may reflect a new screening method for diagnosis, treatment and monitoring, subject to the effective delivery of both projects.

The signing of the Memorandum of Understanding between CRM and FIND, marks an important milestone in achieving the WHO viral hepatitis goals, which is to get 90% of the population screened and diagnosed, and 80% treated by the year 2030.

Hospital Sultanah Bahiyah (HSB) officially operated at its new building complex on 29 July 2007 after a complete transfer and replacing Hospital Alor Setar. Located 6 km from the centre of Alor Setar City, and within the sight of the PLUS North-South Highway, its location makes Hospital Sultanah Bahiyah easily accessible to the public. Surrounded by a vast area of paddy fields, this building complex incorporates 4 main buildings, namely the Medical Support Block, Ward Block, Main Block and Non-Medical Support Block.

In its early days, HSB provided services at secondary and tertiary levels with 10 fields of basic expertise and 28 sub-expertise. Currently, the basic expertise has grown into 17 specialties base with 42 sub expertise. In line with the new technology, this hospital has implemented the online Total Hospital Information System (THIS) on 23 December 2008, thus guaranteeing high quality services. HSB was chosen to implement the Malaysia DRG case-mix program in year 2015 and in 2016, HSB became one of the cluster hospitals, a regional referral centre for 12 health clinics in the district of Alor Setar and Pendang, 8 government hospitals and 11 private hospitals in Kedah, Perlis and Pulau Pinang.

Hospital Sultanah Bahiyah is committed to provide the highest quality of healthcare with affordable specialist care for patients, training for doctors and other healthcare professionals as well as to conduct research according to international standards.



POPULATION SERVED IN 2017

12,279
BIRTH

504,60
Visits to Specialist Clinic

76,206
Inpatient

3983
Staffs

HOSPITAL FACILITY

1084
Bed

40
Wards

MEDICAL WORKFORCE

CLINICAL RESEARCH CENTRE (CRC) / CLINICAL RESEARCH MALAYSIA (CRM) – KEDAH

- Establish on 11 August 2008

- Currently has 3 Medical Officers, 2 Pharmacists, 3 Research Officers, 5 CRM Study Coordinators and 2 Research Nurses.

- The Head of Unit, Datuk Dr. Muhammad Radzi Abu Hassan is a Consultant Physician & Gastroenterologist and Hepatology who actively conducts both investigator initiated research (IIR) and industry sponsored research (ISR).

- On top of ISR, the CRC of Hospital Sultanah Bahiyah had also excelled in IIR over the past 3 years. Some of the major achievements are as follows:
  1. CRC with the highest number of publication per researcher in 2017.
  2. Research papers published in a number of prestigious international journals, including JAMA Oncology, The Lancet, and The New England Journal of Medicine.
  3. Young Investigator Award in the National Conference for Clinical Research (NCCR) received by Mr Chan Huan Keat (CRC's pharmacist) in 2017.
  4. Dato' Eisah's Award for the Best State in Pharmacy Research 2017.

- CRC HSB is also the coordinating center and facilitator for several nationwide patient registry, including:
  1. National Cancer Patient Registry – Colorectal Cancer (NCPR-CC).
  2. National Endoscopy Registry.
  3. National Liver Registry.
  4. National Otorhinolaryngology Registry.
  5. National Obstetrics Registry.

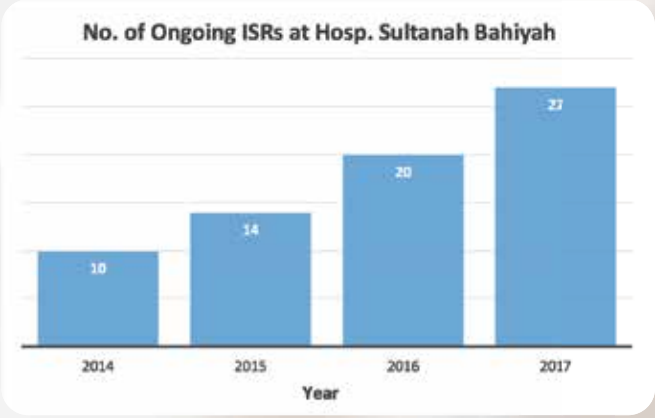
- CRC and CRM at HSB are also actively engaged in R & D training activities. Some of the activities organized or facilitated include:
  1. Good Clinical Practice (GCP) Workshop.
  2. Scientific Writing Workshop.
  3. Introduction to Clinical Research.
  4. Biostatistics Workshop.
  5. Epidemiological Research Method Workshop in collaboration with the Notre Dame University, Indiana, United States.

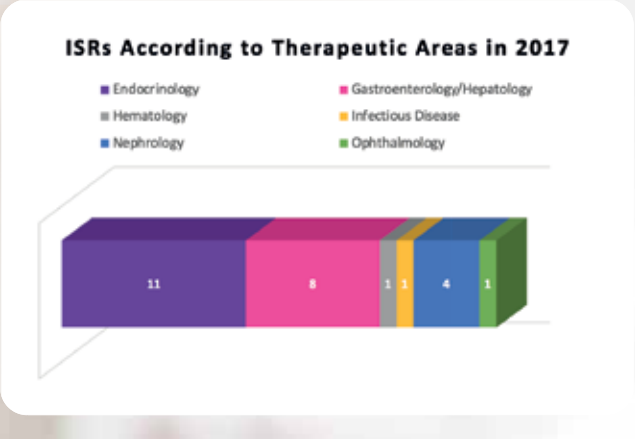
SPECIALTY

- Anaesthesiology
- Cardiology
- Dermatology
- Gastroenterology
- Haematology
- Internal Medicine Physician
- Nephrology
- Neurology
- Neurosurgery
- Obstetrics and Gynaecology
- Ophthalmology
- Orthopaedic Surgeon
- Oral and Maxillofacial Surgeon
- Pulmonary Medicine Physician
- Otolaryngology
- Paediatric / Neonatal
- Paediatric Dental
- Imaging
- Pathology
- Transfusion
- Forensic
- Pharmaceutical Supplies
- Dietetics and Food Services
- Physiotherapy
- Occupational Therapy
- Medical Social Work
- Rehabilitation
- Psychiatry
- Oral Surgery
- Rheumatology
- Endocrinology
- Infectious Disease Specialist

Dedicated Clinical Trial Facility

- The CRC at HSB is equipped with Freezer -20 °C, Freezer -80 °C, Fridge 2-8 °C, temperature monitoring system, temperature-controlled centrifuge, syringe pump, electrocardiograph and emergency cart.
- Documents storage area, rooms for meeting/monitoring with internet access.
- Dedicated area for patient examination and review by investigator.



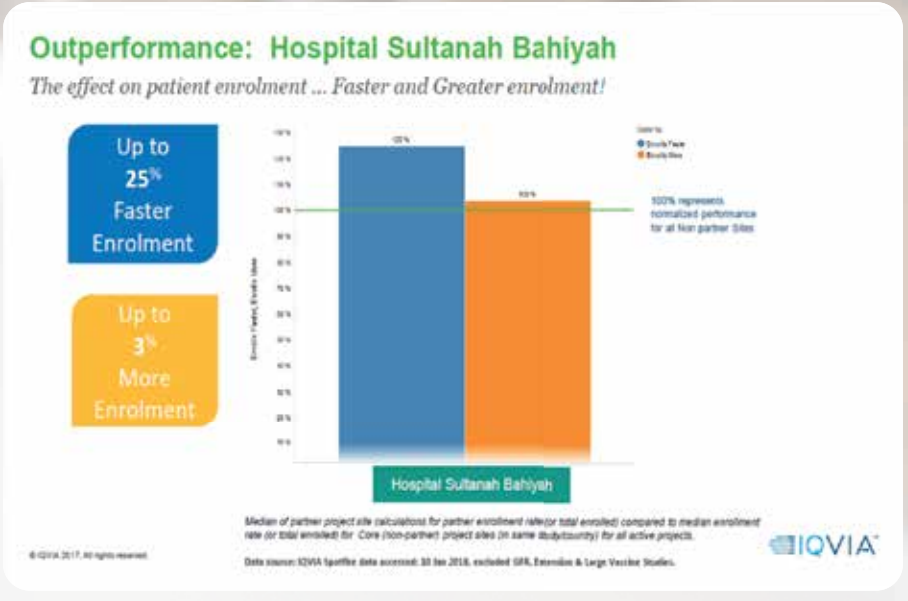


START UP TIMELINES, METRICS, QUALITY AND ACHIEVEMENTS

HSB AS IQVIA PRIME SITE AND PARAXEL PREFERRED SITE

IQVIA Prime Site

- Hospital Sultanah Bahiyah was selected as one of the 12 Prime Site in Malaysia
- Hospital Sultanah Bahiyah enrolled patients up to 25% when faster compared with other sites (2017)
- Hospital Sultanah Bahiyah enrolled up to 3% more patients for all the IQVIA trials (2017)



PARAXEL – Preferred Sites Network

- Preferred Site for clinical trials
- Aim to drive clinical trial efficiencies, improve reliability of delivery and deliver healthcare benefits to patients
- PARAXEL works with the leadership team to increase the flow of clinical trial opportunities

DISCOVER: DISCOVERing Treatment Reality of Type 2 Diabetes in Real World Settings – An Interim Analysis of Baseline Data from Malaysia.

Sothiratnam R[1], Hamad NS[2], Taher SW[3], Vengadasalam P[4], Fam TL[5], Nordin S[6], Mohd Ali N[7], Yin YK[8], Ali N[9], Yahaya Z[10], Nik Kazim NH[11], Kow FP[12], Abdul Kadir A[13], Zakaria R[14], Rajadhyaksha VD[15], Alexander AK[15], Liew J[15], Sia J[15].

[1]Columbia Asia Hospital, [2]Hospital Sultanah Bahiyah, [3]Klinik Kesihatan Simpang Kuala, [4]Hospital Jelapang, [5]Hospital Miri, [6]Hospital Sains Universiti Malaysia (HUSM), [7]Hospital Sultanah Aminah, [8]Klinik Pakar Y&C, [9]Klinik Kesihatan Masjid Tanah, [10]Klinik Kesihatan Sandakan, [11]Klinik Kesihatan Kuala Krai, [12]Klinik Kesihatan Bandar Baru Air Itam, [13]USM Health Campus, [14]Klinik Kesihatan Sultan Ismail, [15]AstraZeneca Malaysia.

Introduction

- According to the DiabCare 2013, despite the effort in improving diabetes care in Malaysia, glycemic control and the prevalence of many diabetes related complications were unchanged over the years.[1] There is still an inertia in getting the patients to clinical targets early with the right treatment .
- Global real-world data on the management of type 2 diabetes (T2D) are limited.

Method

- The global DISCOVER study aims to describe the disease management patterns and a broad range of associated outcomes in patients with T2D initiating a second-line glucose-lowering therapy in routine clinical practice.

- **Primary objective**

- To describe disease management patterns and disease evolution over 3 years in patients with type 2 diabetes initiating a second-line glucose-lowering therapy

- **Secondary objectives**

- To describe patient and treatment characteristics
- To capture treatment changes
- To capture outcomes
  - Microvascular complications
  - Macrovascular complications
  - Hypoglycaemic events
  - Patient-reported quality of life
  - Healthcare resource use
- To assess factors associated with treatment choices
- To assess factors associated with complications

Figure 1: Sites involved in DISCOVER Study

List of sites:

Columbia Asia Hospital, Hospital Sultanah Bahiyah, Klinik Kesihatan Simpang Kuala, Hospital Jelapang, Hospital Miri, Hospital Sains Universiti Malaysia (HUSM), Hospital Sultanah Aminah, Klinik Pakar Y&C, Klinik Kesihatan Masjid Tanah, Klinik Kesihatan Sandakan, Klinik Kesihatan Kuala Krai, Klinik Kesihatan Bandar Baru Air Itam, USM Health Campus, Klinik Kesihatan Sultan Ismail

Figure 2: Enrolled patient YTD Feb 2018

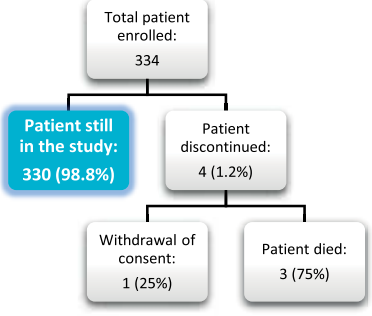
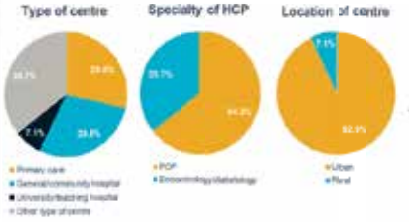


Figure 3: Characteristics of sites and investigators



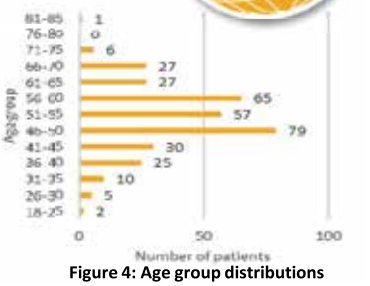


Figure 4: Age group distributions

Table 1: Baseline characteristics at initiation upon initiation of 2nd line therapy

Malaysia (n = 334) ; Mean ± SD	
Sex, male, %	41.9
Mean age, years	53.1 ± 10.5
Mean T2DM duration, years	3.3 ± 3.6
Mean HbA1c %	9.0 ± 2.3
Mean BMI, kg/m²	28.7 ± 7.0
Mean SBP, mmHg	135.7 ± 15.9
Mean LDL-C, mg/dL (mmol/L)	115.9 ± 41.4 (3.0 ± 1.1)
Hypertension, %	63.2
Hyperlipidaemia, %	67.1

Figure 5: Distribution for glucose lowering therapies

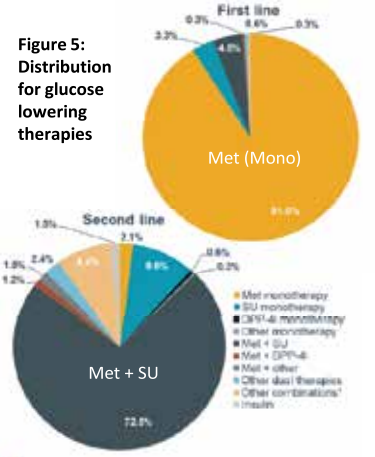
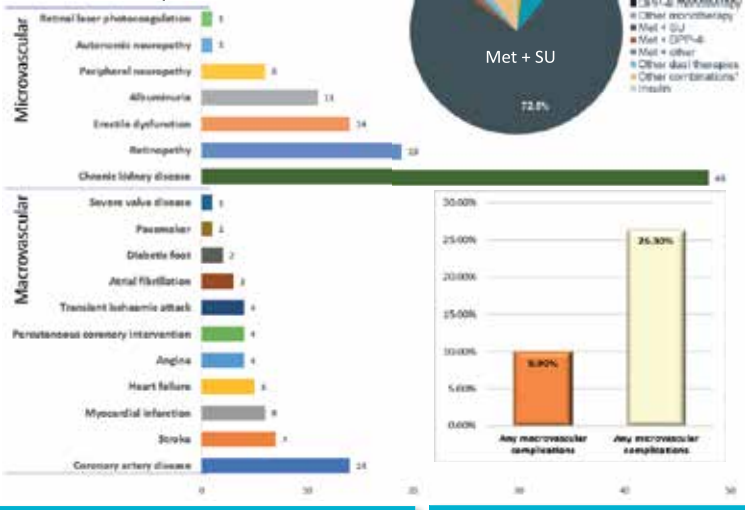


Figure 6: Individuals with microvascular and macrovascular complications at baseline.



Results

- DISCOVER participants had a mean HbA1c of 9.0% at initiation of second-line therapy. Despite the uncontrolled glucose level, treatment inertia was observed when initiation of second-line therapy was at a mean of 3.3 years.
- The most common second-line treatment was the addition of a sulphonylureas (SU) to metformin. This is likely attributed to the wide availability of SUs, where 98.8% of the patients had no access restrictions.
- The rate of microvascular (26.3%) and macrovascular (9.90%) complications was relatively high in this presumably early stage T2D patients.
- Baseline clinical profiles for these patients are consistent with the Asian diabetes phenotypes such as of higher rates of metabolic syndrome and younger onset of T2D, which pose an increased risk for adverse T2D outcomes.[2]

Conclusion

In this study, the T2D patient profile data at initiation of a second line therapy showed poor glycaemic control , multiple comorbidities and high diabetes complications rates, suggesting the need for early diagnosis and intensive management to reduce both micro and macrovascular risk.

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Disclosures

Sothiratnam R is the National Coordinating Investigator for DISCOVER Study. Rajadhyaksha VD, Alexander AK, Liew J, Sia J are employees of AstraZeneca.

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Supported by: AstraZeneca

Presented at the 9th MEMS Annual Congress, 4-6 May 2018, Kuala Lumpur, Malaysia

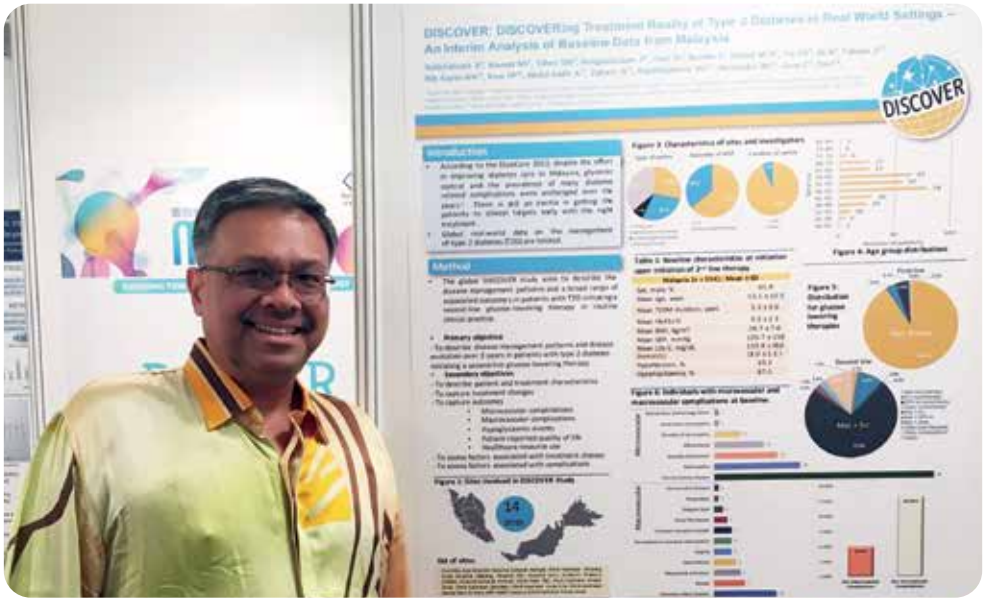
According to the DiabCare 2013, despite the effort in improving diabetes care in Malaysia, glycemic control and the prevalence of many diabetes related complications were unchanged over the years.1 There is still an inertia in getting the patients to clinical targets early with the right treatment. In view that global real-world data on the management of type 2 diabetes (T2D) are limited, the global DISCOVER study was initiated with the primary objective of describing disease management patterns and disease evolution over 3 years in patients with type 2 diabetes initiating a second-line glucose-lowering therapy.[2]

DISCOVER is a global, prospective, non-interventional study conducted in 38 countries, including Malaysia, across six continents. The study has enrolled about 15 000 patients, who will be followed up for 3 years. Data are collected during routine visits from three different sources: electronic medical records, when available, electronic case report forms (eCRFs), which include additional patient clinical data provided by the investigator, and patient-reported outcomes questionnaires completed by patients. [2]

Dr Radhakrishna Sothiratnam, the principal investigator for the DISCOVER Study in Malaysia, has recently presented the baseline Malaysian DISCOVER data at the 9th Malaysian Endocrine and Metabolic Society Annual Congress in Kuala Lumpur, Malaysia on Monday 4 May.

Of the 14 DISCOVER sites in Malaysia, 92.9% were in urban areas, 28.6% were primary care centres, 28.6% were general/community hospitals and 7.1% were university/teaching hospitals. The Malaysian DISCOVER investigators were primary care physicians (64.3%) and endocrinology/diabetology specialists (35.7%). Baseline data were collected from 330 patients in Malaysia, 91.0% of whom received metformin monotherapy as first-line treatment and 72.5% of whom received a sulphonylurea with metformin as second-line treatment. Malaysian patients had worse glycaemic control at baseline than the global DISCOVER population (mean HbA1c level of 9.0% versus 8.3%). At baseline, 9.9% of these patients had macrovascular complications and 26.3% had microvascular complications. The most common microvascular and macrovascular complications were chronic kidney disease (present in 14.6% of patients) and coronary artery disease (present in 4.2% of patients). Overall, these results highlight poor glycaemic control and high levels of vascular complications among DISCOVER patients in Malaysia, which indicates a need for more intensive management of type 2 diabetes.[3]

As part of the continuous effort in providing more real-world data on diabetes, AstraZeneca has also initiated the DISCOVER Global Registry, and Malaysian is once again part of this global initiative. The registry intends to provide real world data on patient characteristics, disease management, healthcare utilization, and outcomes in patients with type 2 diabetes and established micro- and/or macrovascular disease.[4]



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RM 480,000 drug costs reduced to RM1200

CRM Sponsored a Hepatitis C Combination Drug Study

Recovery Rate of 97%

A Dr. Khairul Faizi Khalid (Head of Business Development, CRM) interview with Sin Chew Daily

Combination Usage of Generic Drugs
Malaysian-Thailand 500 people tested

Hepatitis C virus can cause chronic liver inflammation, liver disease, and even liver cancer. Although there are drugs on the market for the treatment of hepatitis C, not many people can afford the treatment costs. A full 12-week course of treatment is around US$ 120,000 (around RM 480,000).

In order to tackle the challenges of increasing number of hepatitis C patients and high medical expenses, Clinical Research Malaysia (CRM), Drugs for Neglected Diseases initiative (DNDi) (a non-profit research and development organization) and Pharco Pharmaceuticals (Pharco) (an Egyptian pharmaceutical company), have signed a collaboration agreement to manufacture and supply a new hepatitis C treatment regimen. In partnership with the Malaysian Ministry of Health (co-sponsored by CRM), DNDi is currently running clinical trials testing a potentially pan-genotypic treatment, combining the drug ravidasir, produced by the Egyptian drug manufacturer Pharco Pharmaceuticals, with the existing hepatitis C medicine sofosbuvir.

According to DNDi, based on the interim results from the Phase II/III STORM-C-1 trial, 97% of patients enrolled in a full 12-week course of treatment were cured with the new combination of drugs. Most importantly is that this new treatment only cost US$300 (around RM1200), compared to US$120,000 for a full 12-week course treatment in Malaysia currently.

This trial recruited 500 people in Malaysia and Thailand within 1 year. Out of 500 people, 400 are Malaysian. Hospitals involved in this project include Hospital Selayang, Hospital Ampang, Hospital Sungai Buloh, University of Malaya Medical Centre, Hospital Tengku Ampuan Afzan from Kuantan, and Hospital Sultanah Bahiyah from Alor Setar.

Exploring shortened treatment
Extend genotype

Clinical trial on the new drugs is still ongoing. The next phase is to find the bioequivalent of the drug. The collection of blood samples for plasma level studies will be handled by Hospital Ampang.

If the new drug is confirmed to have the same bioequivalent properties to the original drug in terms of safety, tolerability and efficacy, then patients will be able to receive high-quality drugs at an affordable price, which is undoubtedly good news.

We have just concluded a meeting with DNDi and mentioned more possibilities for the efficacy of new drugs, such as shortening the course of treatment, and we found that some patients have no signs of viral infection at the eighth week of treatment. If the new drug duration can be shorten from its original 12-week course, then the patient can save on the treatment fee.

The rate of new drug treatment depends on the patient's own viral genotype, and most of the Malaysian patients belong to genotypes 1 and 6. Therefore, we will also explore the possibility of extending new drugs to genotypes 2 and 3 to achieve a broader coverage level.

The Government issued a compulsory license
Resolve Hepatitis C Patients' Problems

We are proud to inform that Hepatitis C patients in Malaysia are the first recipient of this new drug treatment. Usually, new drugs are introduced to Malaysia after approval by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA). By then, it may be too late for patients.

CRM Head of Business Development, Dr. Khairul Faizi Khalid (from left, no.3), Head of Finance and Information Technology, Mr Yau Yit Huan (from left, no.2) and Business Development Executive, Syed Hamzah (from right, no 3) visited Sin Chew Daily and was welcomed by Chief Editor of Sin Chew Daily (right, no. 4), Chief Editor of "Easily Page" and reporters

Where to Find Clinical Studies?
Check Online to Find Out

In October last year, Clinical Research Malaysia added a brand-new function to its official website http://www.clinicalresearch.my/. It is a prominent column in the lower right corner of the web page, with the tab "Find a Clinical Trial". This new function brought good news to critically ill patients, especially those unable to afford expensive medical treatments. Patients and their families can find out which government or private hospitals provide new research or treatment options according to their medical conditions.

In the website, the users can select between "Healthy Volunteer" or "Patient" and proceed to fill in their personal information to register themselves. Based on the information provided in the website, for "Healthy Volunteers", they can choose Ampang Hospital in Selangor, three different hospitals in Penang and a hospital located in Kuching. For "Patients", the diagnosis of illness and their location must be filled in order to search for the appropriate hospital. The participating hospitals in this clinical trial cover all parts in Malaysia, which include hospitals in major cities, as well as several large private hospitals.

The clinical trials listed on the website covers several diseases, such as acute coronary syndrome (ACS), nonalcoholic steatohepatitis (NASH), IgA renal disease, lupus nephritis, anaemia, diabetic nephropathy, heart failure, glaucoma, breast cancer, lymphoma, thrombotic microangiopathy (TMA), thalassemia, leukemia, hepatitis C disease, prostate cancer, erosive esophagitis, depression, venous thromboembolism, stroke, etc. It covers almost all critical diseases that Malaysians have regardless of race, environment and gender. Unfortunately, as there is lack of publicity of this new function, not many people know about it.

Not a "Guinea Pig"
Careful follow-up by the Medical Team

However, not every applicant can participate in these clinical trials. Applicants must go through a series of review. Those who are interested can use this new feature in the website to submit their applications, as well as contact the major government hospitals for enquiries.

In the past, many people lacked understanding of clinical trials. Their perceptions of clinical trials are that they are being experimented on like a guinea pig. There is a lack of understanding on newly developed drugs or treatment programs and assume it to be a high-risk procedure. In fact, patients who participated in clinical trials may not only obtain early results from the new drug treatment from the pharmaceutical company, but the results can also be followed up carefully through the Medical Team as well. Most importantly, these drugs have actually passed through layers of checks, and patients will not be treated as a "guinea pigs". Therefore, clinical trials may be a source of hope for those with critical diseases."

A Syed Hamzah Syed Noordin (Senior Business Development Executive, CRM) interview with Sin Chew Daily

Pinktober: Be Aware of Breast Cancer

By Soon Wen Xian

It's that month of the year again where we see pink-coloured ribbons everywhere; on the roads, in shopping malls and of course, in clinics and hospitals too. The month of October is – as known by many, especially by females – as the month for Breast Cancer Awareness. Unlike my female counterpart, I used to not really care about the pink-coloured ribbons. At most, I only know that it represents breast cancer and nothing else. But a recent experience with breast cancer patients has truly became an eye-opener for me -- I became an advocate almost instantly. So, with my story being told here, I hope to remind our beautiful ladies out there to be aware of breast cancer and if you have an opportunity to get a medical check-up this month, please get yourself checked.

As a prelude to my story, let me share you something about cancer from a clinical research perspective because I'm quite familiar with this industry. Firstly, cancer is among the most popular disease profile within the clinical research industry. As most of us know, we still do not have a one-drug-cure-all for cancers. Some cancer patients are lucky where their body responds well to treatments currently available but for the most cases, patients are usually not that fortunate. But don't give up hope too soon because scientists and doctors all around the world are working around the clock, looking for new compounds to help cancer patients. For pharmaceutical companies, breast cancer is one of the most important disease in view of patient population. For example, in Malaysia, 1 in 20 females are at risk of breast cancer. Nonetheless, the survival rate among breast cancer patients is increasing due to the extensive research being done by scientists and doctors throughout the years. Current treatments of varying effectiveness ranging from surgical therapy, chemotherapy, radiation therapy, hormonal therapy and targeted (biological) therapy are available at disposal.

During my tenure in the clinical research industry, I was given an opportunity to handle a clinical trial involving breast cancer patients. Interestingly yet unfortunate, in this trial, there was a patient who was diagnosed with a stage 3/4, unresectable with triple negative breast cancer. Sounds horrendous, right? Well, it is. So now, the question that may arise is: what is a triple negative breast cancer? Here is where it gets a little bit clinical. When a patient has been diagnosed with a breast cancer, the doctor will usually request a biopsy to be conducted on the patient to test on the cancer cells. This test is to identify the presence of three distinct receptors; oestrogen receptors (ER-), progesterone receptors (PR-), and HER2 receptors (HER2-). Identifying the presence of these receptors are very important as it determines which treatment is suitable for the patient. If receptors ER- and PR- are present in the cancer cell, the patient will be given hormonal therapy. If receptor HER2- is present, then the patient will be receiving a targeted treatment. But if there are no receptors found on the cancer cell, hormonal nor targeted treatments will work. This is what we call a triple negative breast negative; absence of all three receptors. Triple negative breast cancer patients will usually receive a combination of therapies such as chemotherapy andradiotherapy.

According to a review article by Jr Dean et al[1], 17% of Malaysian women with breast cancer are presented with triple negatives in 2014. It was also noted that younger women are more prone to triple negative breast cancers, with a poorer prognosis.

Initially, we had only committed to recruit 20 breast cancer patients for our clinical trial but as the trial went on, our recruitment went better than expected. In the end, we managed to recruit over 30 patients. This was good because with more patients recruited in a clinical trial, we will be able to provide a much significant result if a treatment works against cancer – a breakthrough might also be possible. Nonetheless, it was quite sad to see that our youngest patient in the trial was born in 1992. Although most of our patients are more than 50 years old, some of them are still actually in their 20s or 30s. The clinical trial is still at treatment stage but unfortunately, less than 30% of the recruited patients remain.

This was personally a very difficult clinical trial project for me. Recruitment rate is very important to measure the trial's performance but with more people recruited, that means more people are being diagnosed with cancer in Malaysia. Every time I visit the site, the number of patients may have increased when there are new patients. Then again, the number of patients may have also decreased when patients fail the treatment. It's a difficult feeling; you want to help people to find a better treatment to fight their disease but at the same time you feel bad when you see more people are being diagnosed with cancer joining in the trial. Sometimes, there can be good news during the clinical trial where patients get better with treatment but there are also times where the treatment just doesn't work on certain patients. This is a challenge we face in clinical trials. The human biology is complex, the disease we are fighting is complex, but we can never stop trying because hope is always there.

Breast cancer is not only attacking more and more ladies, but it also targets young people. Most cancers are treatable if detected early. So, we should never feel complacent whenever we feel that there is something wrong with our body. Get yourself checked regularly. Make it a commitment on every October to see a doctor. Early stage cancer is usually detected accidentally during check-ups. If detected early, chances are that we can still stop it from spreading.

Again, October is the month of breast cancer awareness. I hope our ladies and – with a strong emphasis here - our men will take this opportunity to join in the campaign and learn what breast cancer is, what options are there for treatment, what ongoing clinical trials are there for breast cancer, how to detect it early, and so on. Although clinical research is making good progress in finding a better and much effective treatment, I think it is still better for individuals to be active in checking their body for any traces of cancer. The earlier we detect the cancer, the better options there are to treat and potentially cure ourselves from cancer. Here is to a better care for our body and to a better life for our soul.

Evolution of Clinical Trial Agreement Review in Malaysia Through Clinical Research Malaysia

Sep 21, 2018 | By Nurul Atiqah Abd Rahman, Norafizaa Yusop | Applied Clinical Trials

Clinical trials are serious activities where humans are the subject matter in helping to answer scientific hypotheses. To regulate the conduct, relationships, responsibilities, and obligations of the parties involved in the clinical trial, the Clinical Trial Agreement (CTA) must be in place. The parties in a CTA are not usually limited to sponsors or contract research organizations (CROs), but also include institutions and principal investigators. The Malaysian Guideline for Good Clinical Practice, has defined the CTA as "A written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract."[1]

The above definition widens the scope of CTAs, where apart from obligation of parties, the clinical trial budget must also be enumerated clearly in the Agreement.

Halsbury Laws of England has also defined the meaning of agreement in general: "A contract or an agreement is usually reached by the process of offer and acceptance and the law requires an offer on ascertainable terms which receives an unqualified acceptance from the person to whom it is made."[2]

In Malaysia, clinical trials are developing rapidly, which has allowed Malaysia to become a preferred site for clinical trials sponsored by multinational sponsors or CROs.[3] With that, Clinical Research Malaysia (CRM) is established as a one stop shop to assist the principal investigators and the industry in matters related to clinical trials. The CRM Legal and Regulatory Affairs' role is important in providing CTA Review. The experienced CRM Legal and Regulatory Affairs department is equipped with detailed and current legal knowledge that results in a thorough and prudent review of the CTA by respecting all the applicable laws and regulations.

It is most important for the CTA to be drafted in a language that is understandable to all parties. It needs to be written clearly, limiting and defining any legal terms used. Sponsors and CROs share the same interests in relation to clinical trials, which are:

(a) collecting accurate data to support their application for marketing approval of their investigational product
(b) protecting confidential information and intellectual property
(c) complying with the applicable laws and regulations

On the other hand, from clinical trial site perspectives, their interest lies among compliance with the protocol and regulations, which includes:

(a) to be fairly compensated for their work
(b) indemnity (subject illness, injury, or death due to participation in the study or as a result of the investigational product) and sufficient insurance coverage protection to the site, principal investigator, and principal investigator's team
(c) the ability to publish study results
(d) payment for subject in relation to the study[4]

When working towards a contract agreement between sponsors/CROs and clinical trial sites, there needs to be two-way communication and negotiation. Without having a clear and straight forward language, it is difficult to finalize the CTA in a short time. Therefore, it is essential to prepare when negotiating a contract with sponsors and CROs for items and changes that are requested. Apart from that, with the presence of experienced, proactive, and efficient CRM Legal and Regulatory Affairs Departments in reviewing CTA, the review and negotiations of CTA are done in a short period of time.

In ensuring a short timeline of CTA Review, a fixed 14-day calendar timeframe is introduced so that the site initiation visit can follow through as planned under the protocol. All CRM's legal personnel shall maintain a timeline tracker to make sure the 14-day calendar timeframe is achieved for any one CTA review. However, it is still subject to the budget negotiation between all parties, as the clinical trial budget is incorporated as part of the CTA.

Methodology

The total number of CTAs that have been reviewed by CRM between 2012 and 2017 was compiled and will be illustrated in Schedule 1. This is based on the retrospective data collection by CRM.

From 2012 to 2017, a total of 457 CTAs have been reviewed by CRM.

Year	CTA reviewed by CRM
2012	54
2013	83
2014	83
2015	86
2016	68
2017	83

Schedule 1

The number of CTA review days is crucial to start a clinical trial at the site because it will affect the activities of the trial. The study cannot commence without execution of the CTA. The data on review days from 2012 to 2017 are illustrated in Schedule 2 below.

From 2012 to 2015, CRM took a longer time to review the CTAs—it took 59 days on average to review the CTA until endorsement. The CTA review days decrease from 2016 and were reported as 13 days in 2017.

Year	CTA reviewed timeline by CRM (average time by days)
2012	58
2013	42
2014	42
2015	92
2016	29
2017	13

Schedule 2

The substantial improvement is mainly because:

(a) All CRM Legal and Regulatory Affairs personnel have their own Key Performance Index to review the CTAs within 14 days.
(b) In 2015, CRM Legal and Regulatory Affairs Department developed an online CTA Review System expediting the CTA review days from 59 to 13. The online review system was launched in March 2016. The online system is our own purchased internal system, where all the CTAs for Malaysian Ministry of Health sites, specifically for industry sponsored research, will be submitted in the system by the clinical research assistant from sponsors and CROs for CRM Legal and Regulatory Affairs Department's review.
(c) The CRM Legal and Regulatory Affairs Department had also organized the CTA online review system workshop for sponsors and CROs on how the system works and their role as the external end user of the system. The system was fully utilized in 2017 and has shortened the timeline for CTA review.
(d) CRM expanded the Legal and Regulatory Affairs Department manpower from 1 in 2012 to 3 in 2017 which contributed to expedite CTAs review.

Conclusion

The four actions described above have reduced the CTA review days. Reduction time in review days improves the study start-up time from the CTA review point of view. This evolution enticed more sponsor and CROs to bring more clinical trials to Malaysia.5The unnecessary delays in finalizing the CTA should be avoided. As a result, the nation benefits with faster and more clinical trials for doctors and patients to include in their treatment options.

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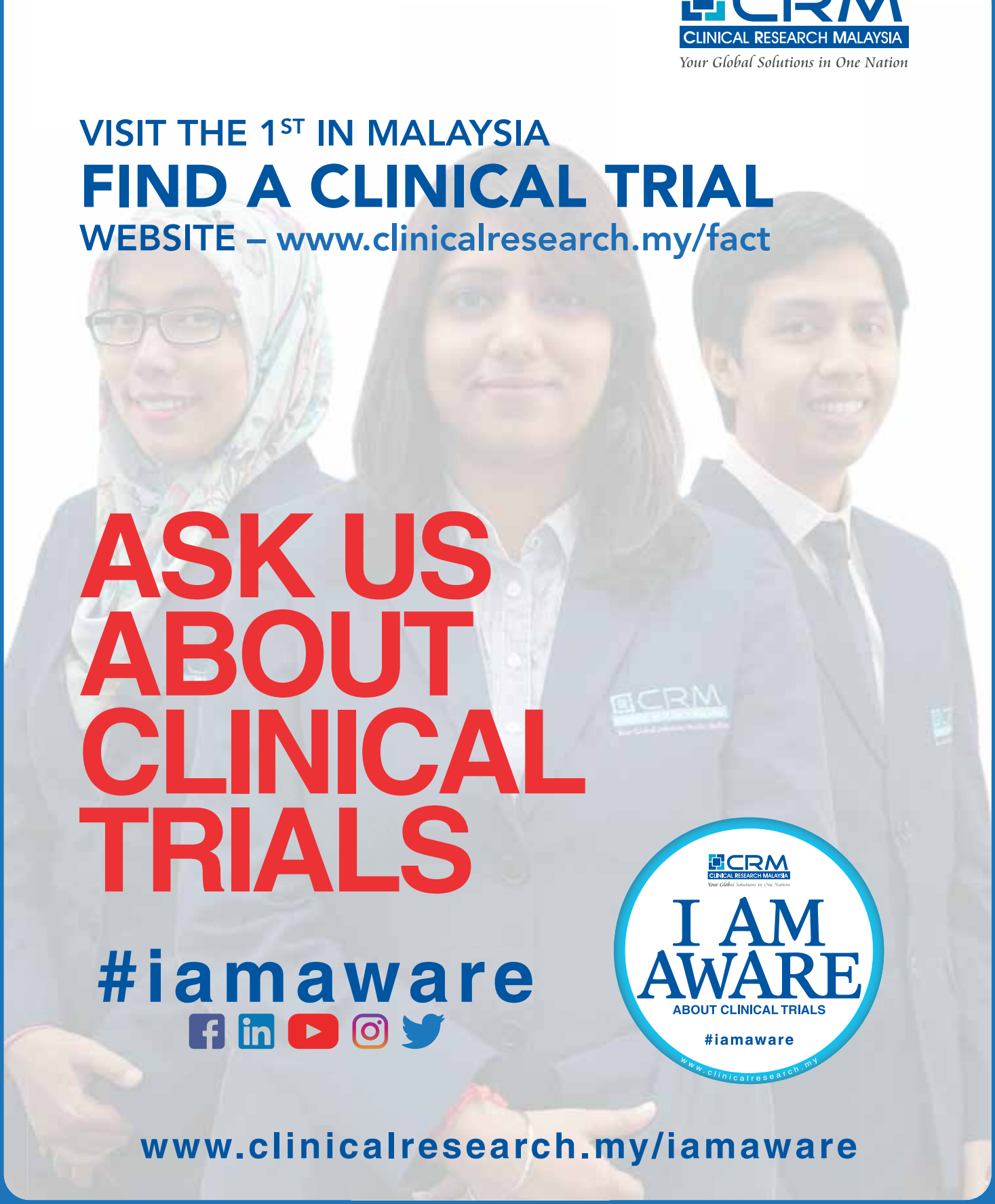

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