



# ANNUAL REPORT 2018

UPDATED: 18 JUNE 2019

# About our report

Clinical Research Malaysia (CRM) is proud to share our achievements of the past year's successes in this 2018 Annual Report. We encourage our stakeholders, industry partners, investigators and members of the community to take a moment to read our annual report, which contains information about the important work that our organization does to build a comprehensive research ecosystem in Malaysia. It also features the work and achievements of CRM.

For industry sponsors, the success of a sponsored research depends upon choosing the right country to conduct clinical trials. Speed, quality and reliability are essential criteria for a site to be awarded the study. Malaysia offers a compelling package to sponsors and contract research organizations (CROs) when it comes to conducting sponsored research.

Simply put, a very strong emphasis on patient safety and benefit is combined with a well-developed and equipped healthcare system that is manned by well-trained, highly qualified and English literate medical professionals. Moreover, Malaysia's multi-ethnic population provides sponsors and CROs with access to genetic diversity while the costs of conducting clinical trials are very competitive when compared to neighbouring countries in the region.

The long-term focus by the Malaysian Government is to make Malaysia a significant global player in clinical research and this is made possible through the establishment of CRM. CRM provides advance global health solutions for a brighter, more hopeful future for the people by providing speedy and reliable end-to-end clinical research support. CRM works together with its partners to create an impetus in delivering better services to its end clients and at the same time creating high-skilled job opportunities.

This annual report, we will highlight CRM's milestones to showcase Malaysia's potential as the preferred hub for conducting clinical trials.



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### "CRM, a Globally Trusted Research Organization"

In this edition of the annual report, I would like to highlight on how rapidly CRM has grown and significant our achievements have been in 2018. The company is now paving the way for Malaysia to become a global leader in the clinical research industry.

Since 2015, the CRM 5 key strategies have seen a substantial growth in terms of the number and quality of investigators, clinical research sites, the number of sponsored research conducted, the relationship we have with our stakeholders, the level of public awareness of clinical research, and the talents that we have developed. These, together with four of our business core values (transparency, honesty, accountability and trustworthiness) became the basis of the continuous success of CRM in 2018.

The year 2018 has seen CRM taking strong strides in our efforts to build a global trusted research organisation. Firstly, we have made it a goal for us to be accredited with the ISO 9001:2015 Quality Management System where this will ensure consistent standard quality of clinical trial conduct at all sites in Malaysia. Secondly, we have signed a total of 6 MoUs (Memorandum of Understanding) with various leaders in the industry around the globe; from Hematogenix in the USA, Novotech in Australia, intellim in Japan, with IQVIA Global Early Phase Oncology Network, the Foundation for Innovative New Diagnostics (FIND) and The First Affiliated Hospital of Zhejiang University in China. These strategic partnerships solidified CRM status as a major research organization globally. In addition, CRM was recently recognised by IQVIA as having the fastest start-up time in Southeast Asia, and the 7th fastest globally, contending European countries. On that note, I am also proud to announce that as of January 2019, Clinical Research Malaysia is now officially ISO 9001:2015 accredited! We hope with this accreditation our stakeholders will have a stronger confidence in CRM's services and capabilities. My sincere gratitude to all 175 CRM personnel nationwide whose commitment and hard work have made all this possible.

Finally, I would like to thank all members of CRM's Board of Directors chaired by the Honourable Datuk Seri Dr. Haji Dzulkefly bin Ahmad, Minister of Health Malaysia, for their support and guidance. My heartfelt gratitude also goes to our stakeholders which comprise of multinational research companies, contract research organizations, academia, institutions, investigators, clinical research personnel and all those who have directly or indirectly contributed to the conduct of sponsored research in Malaysia. Indeed, our achievements today would not have been possible without your hard work and dedication. My sincere thanks to all who have contributed their valuable input to this report.

Dr. Akhmal Yusof CEO, Clinical Research Malaysia



# **Board** of Directors

CRM's Board of Directors comprised of prominent individuals who are representatives from the Ministry of Health, university hospitals and the pharmaceutical industry.



Chairman

YB Datuk Seri Dr. Dzulkefly Ahmad

Minister of Health, Malaysia



Y. Bhg. Dato' Seri Dr. Chen Chaw Min Secretary General, Ministry of Health, Malaysia



Y. Bhg. Datuk Dr. Noor Hisham Abdullah Director General of Health, Malaysia



**Y. Bhg. Dato' Dr. Goh Pik Pin**Director, National Clinical Research Centre,
Malaysia



Y. Bhg. Datuk Dr. Shahnaz Murad Former Deputy Director General of Health (Research & Technical Support)



Y. Bhg. Prof. Datuk Dr. Adeeba Kamarulzaman Dean of the Medical Faculty at Universiti Malaya



Mr. Ewe Kheng Huat Executive Director of the Pharmaceutical Association of Malaysia

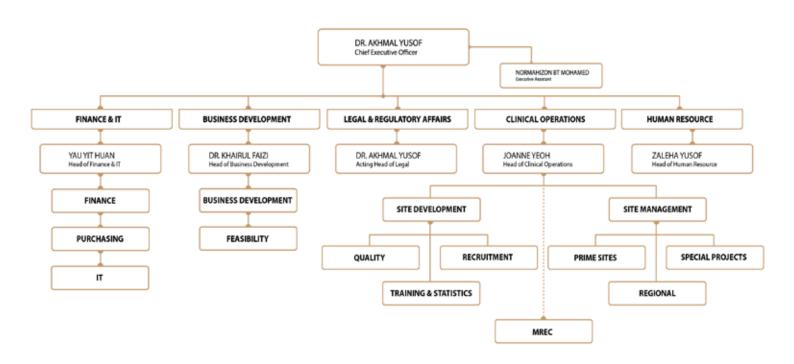


Prof. Dr. Abdul Rashid Abdul Rahman Medical Director and Senior Consultant Physician, An Nur Specialist Hospital



Prof. Datuk Dr. A. Rahman A. Jamal Pro Vice Chancellor, Universiti Kebangsaan Malaysia (UKM)

# **Organizational Chart**





# **Performance Overview**



CRM's vision by 2020 is to 1) attract 1000 new and ongoing sponsored research, 2) achieve a gross national income (GNI) of RM578 million and 3) develop 1000 high skilled jobs in the clinical research industry. In 2018, the recorded GNI totalled over RM378.2 million, an increase of RM127.7 million from 2017, and 1620 number of skill jobs in clinical research has been created.

CRM also compiles and tracks the number of sponsored research from the Medical Research and Ethics Committee (MREC) as well as all Institutional Review Boards/Independent Ethics Committees (IRB/IECs) in Malaysia. These numbers are reported annually to the Malaysian government via CRM. After recording 171 in the number of sponsored research in 2017, 2018 has shown an almost similar number of sponsored research taking place (Figure 1).

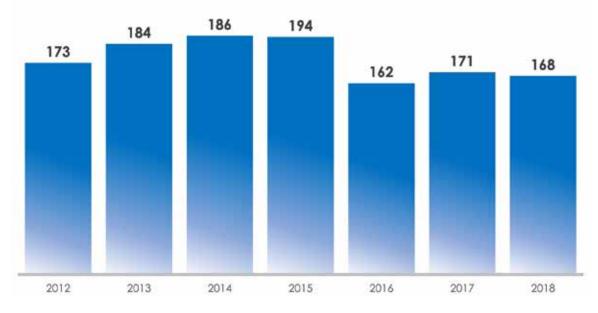


Figure 1: Number of Sponsored Research from 2012 – 2018

### **Performance Overview**

The number of sponsored research conducted at Ministry of Health (MOH) sites have seen a healthy growth in 2018 in comparison to the previous year. In 2018, a total of 120 MOH hospitals and health clinics was reported to have conducted sponsored research, up from 110 in 2017 (Figure 2).

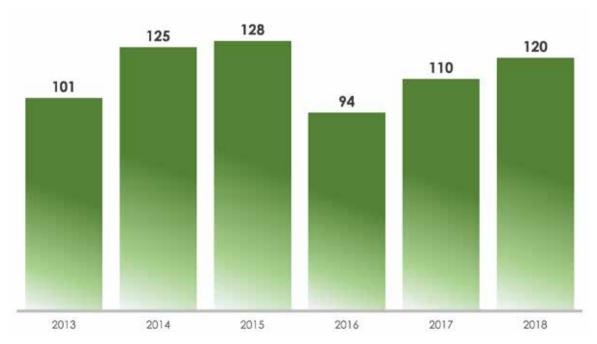


Figure 2: Number of Sponsored Research conducted in MOH from 2012 – 2018

# **Types of Clinical Trials**

Interventional trials accounted for the largest proportion of trials in Malaysia in 2018, with Phase III trials recording the highest number of trials followed by phase IV, bioavailability/bioequivalence (BA/BE) studies, phase II, phase I and pre-clinical studies (Figure 3).

Out of all interventional trials, 64 trials (51.6%) involved new investigational products, 37 (29%) are BA/BE studies and 16 (12.9%) are medical device trials (Figure 4). New investigational products are generally comprised of drugs, biologics, biosimilars or supplements.

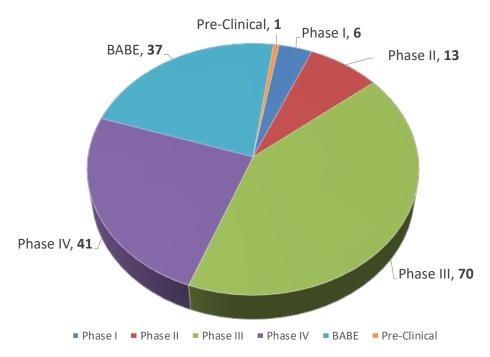


Figure 3: Breakdown of interventional studies according to phases

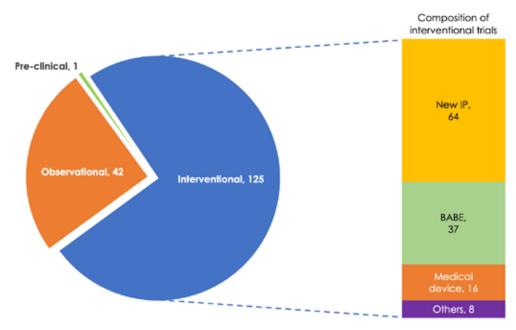


Figure 4: Classification of clinical trials conducted in Malaysia in 2018

#### **Performance Overview**

Disease patterns in Malaysia are almost like those in developed countries. Malaysian patients have similar unmet medical needs that these countries have. Cardiovascular disease and cancer are the major cause of mortality and morbidity in Malaysia. The high incidence of these noncommunicable diseases provides a large patient pool for clinical trials in these therapeutic areas. In 2018, cardiovascular trials accounted for the highest number of trials followed by oncology trials (Figure 5), a pattern which is similarly seen in the previous years. 2018 has also seen a rise in the number of haematology trials from only 4 in 2017 to 13. Infections and Infectious disease trials have also recorded an increase number of trials in 2018 where there were 15 trials compared to only 6 the year before. Meanwhile, Sarawak General Hospital & Heart Centre was recorded to have the most number of trials in Malaysia for 2018 followed by Hospital Pulau Pinang and University Malaya Medical Centre (Figure 6).

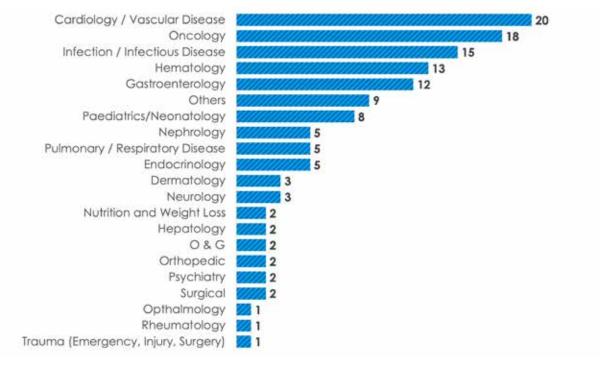


Figure 5: Number of clinical trials conducted according to therapeutic area in Malaysia

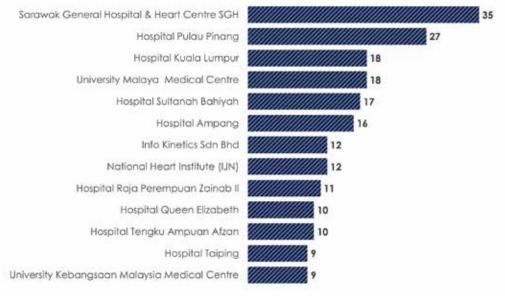


Figure 6: Top Sponsored Research Sites in Malaysia for 2018

## Top Sites according to Therapeutic Areas

Below are the top clinical trial sites in 2018 in the field of Oncology, Infections & Infectious Diseases, Cardiology/Vascular Disease, Gastroenterology/Hepatology, and Haematology/Hemato-Oncology. Besides these sites, there are also other sites with experience in these respective therapeutic areas. CRM has been involved in the trials at most of the Ministry of Health sites, whereby it has assisted investigators in the review of the study budget and clinical trial agreement, as well as in providing study coordinators.

#### **ONCOLOGY**

- Sarawak General Hospital
- Pantai Hospital Kuala Lumpur
- Hospital Tenaku Ampuan Afzan
- Hospital Kuala Lumpur
- Mount Miriam Hospital Cancer Centre
- Hospital Sultan Ismail
- Mahkota Medical Centre
- Institut Kanser Negara
- Hospital Raja Perempuan Zainab II
- Hospital Sultanah Bahiyah
- Hospital Wanita dan Kanak-kanak Sabah

### INFECTIONS & INFECTIOUS DISEASE

- Institut Perubatan Respiratori
- Hospital Raja Permaisuri Bainun
- Hospital Seberang Jaya
- Hospital Shah Alam
- Hospital Sibu
- Hospital Tuanku Ja'afar
- University Kebangsaan Malaysia Medical Centre
- University Putra Malaysia

### CARDIOLOGY/VASCULAR DISEASE

- Institut Jantung Negara
- Heart Centre Sarawak General Hospital
- Hospital Serdang
- University Malaya Medical Centre
- Hospital Queen Elizabeth II
- Pantai Hospital Kuala Lumpur
- Hospital Tengku Ampuan Afzan
- Hospital Pulau Pinang
- Hospital Raja Perempuan Zainab II
- Sunway Medical Centre
- Hospital Universiti Teknologi MARA

#### GASTROENTEROLOGY/HEPATOLOGY

- Hospital Sultanah Bahiyah
- Hospital Ampang
- University Kebangsaan Malaysia Medical Centre
- Hospital Pulau Pinang
- Hospital Raja Perempuan Zainab II
- Hospital Taiping
- Hospital Selayang
- Klinik Kesihatan Pandamaran

#### HAEMATOLOGY/HEMATO-ONCOLOGY

- Hospital Ampang
- Hospital Queen Elizabeth
- Hospital Pulau Pinana
- Hospital Sultanah Aminah
- Hospital Kuala Lumpur
- Sarawak General Hospital
- Hospital Sultan Ismail
- Universiti Kebangsaan Malaysia Medical Centre
- Hospital Wanita dan Kanak-kanak Sabah
- Hospital Raja Permaisuri Bainun
- Hospital Sultanah Nur Zahirah
- Hospital Universiti Sains Malaysia
- University Malaya Medical Centre

### **Feasibility Study Report**

Feasibility studies are the gateway to bringing in more clinical trials to Malaysia. It is not only a tool to assess whether a trial is possible to be conducted in Malaysia, but also a method to promote that possibility to sponsors and CROs who may not be familiar with Malaysia's demographics, disease pattern and research sites.

CRM's feasibility service is provided complimentary to sponsors and CROs who may be interested in conducting clinical trials in Malaysia. Parallel with the growth of sponsors and CROs who have utilized CRM's services, the number of full feasibilities received from 2015 to 2018 recorded a steady growth from 80 in to 2015 to 115 in 2018 (Figure 7). Most feasibility studies received in 2018 were studies in oncology followed by haematology, paediatrics, gastroenterology, nephrology and infectious diseases (Figure 8).

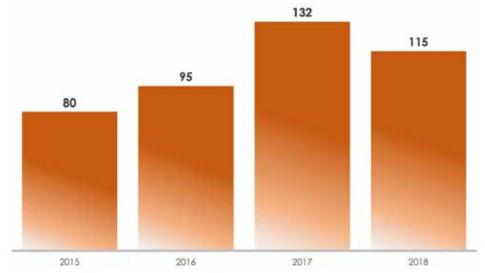


Figure 7: Full feasibilities from 2015 – 2018

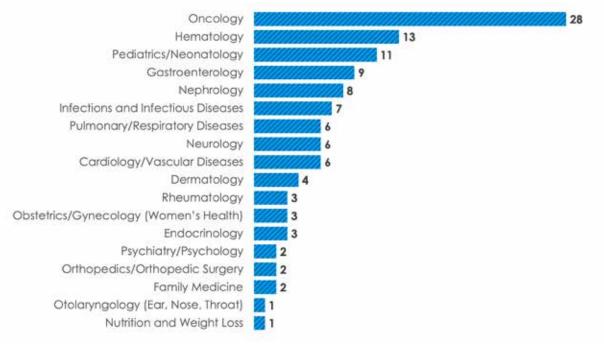




Figure 8: Full feasibilities received in 2018 by therapeutic area

Table 1 shows the top 5 indications of the 5 highest therapeutic areas of feasibility received from 2015 to 2018.

Table 1: Top indications from the five highest feasibilities by therapeutic area received from 2015 to 2018

Top 5 Full Feasibilities Received from 2015–2018 by Therapeutic Area	Top 5 Indications (n)
Oncology	<ul> <li>Non-Small Cell Lung Cancer</li> <li>Breast Cancer</li> <li>Gastric/Gastroesophageal Junction Carcinoma</li> <li>Colorectal Cancer</li> <li>Liver Cancer</li> </ul>
Haematology	<ul> <li>Lymphoma (B-cell Lymphoma, T-Cell Lymphoma, Follicular Lymphoma, Non-Hodgkin Lymphoma)</li> <li>Haemophilia</li> <li>Acute Myeloid Leukemia</li> <li>Thalassemia</li> <li>Paroxysmal Nocturnal Hemoglobinuria</li> </ul>
Gastroenterology	<ul> <li>Ulcerative Colitis</li> <li>Crohn's Disease</li> <li>Hepatitis B</li> <li>Non-Alcoholic Steatohepatitis (NASH)</li> <li>Diabetic Gastroparesis</li> </ul>
Paediatrics/Neonatalogy	<ul> <li>Paediatric Respiratory Syncytial Virus</li> <li>Type 2 Diabetes Mellitus (in paediatric population)</li> <li>Pneumococcal Vaccine</li> <li>Paediatric Partial-onset Seizures</li> <li>Paediatric Lymphoma</li> </ul>
Infectious disease	<ul> <li>Ventilator Acquired Pneumonia</li> <li>Influenza A</li> <li>HIV</li> <li>Antimicrobial Resistance</li> <li>Malaria</li> </ul>

### **Growth of Sponsors and Contract Research Organizations**

Since its establishment in June 2012, CRM has been promoting its core services to local and global sponsors and CROs. Besides offering complimentary feasibility studies to companies intending to conduct clinical trials in Malaysia, CRM also facilitates its clients with CTA review, budget management, placement of study coordinators and archiving services. In 2018, 179 sponsors and 55 CROs utilized CRM's services. This shows a 5 times growth for sponsor and more than 2.5 times growth for CRO since 2014 (Figure 9).



Figure 9: Sponsors and CROs who utilised CRM's services

### **Growth of CRM Study Coordinators**

In its infancy in 2012, CRM had 22 study coordinators that were placed throughout Malaysia at various sites conducting sponsored research and this number has grown to 128 in 2018 (Figure 10). CRM has expanded its operations beyond the realm of Ministry of Health sites. It had received requests to support investigators and sites in the Ministry of Higher Education hospitals such as Hospital University Kebangsaan Malaysia (HUKM) and private hospitals resulting in a significant growth in placement of study coordinators at clinical trial sites. To this end, CRM has continued to provide relevant trainings to its study coordinators to uphold the quality of each trial.

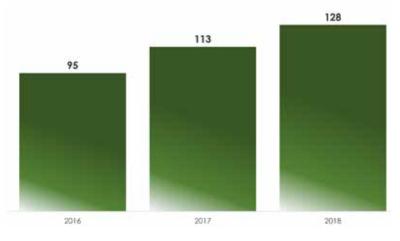


Figure 10: Growth of Study Coordinators at CRM from 2016 – 2018

### **CRM's Presence in National and International Meetings**

CRM participated in various national and international meetings and conferences and utilized these platforms to bring Malaysia's clinical research capabilities to the global audience. CRM has also conducted several roadshows at various MOH hospitals to generate interest in clinical research among researchers and healthcare professionals locally.



### ACOS 2018, Chiang Mai, Thailand

February 23-25

CRM was invited to give a talk at the 13th Asian Clinical Oncology Society 2018 Meeting in Chiang Mai. CEO, Dr Akhmal Yusof presented a talk on how Industry sponsored research benefited the Malaysian population socieconomically - more than RM240Million in investment and estimated RM40million in cancer drugs alone for the past 5 years.



### 4th ICPOEP, Hong Kong

March 1

The 4th International Conference on Phase 1 and Early Phase Clinical Trials (ICPOEP) was organized by the University of Hong Kong Clinical Trials Centre. CRM was present to exchange ideas and experience on early phase studies with key opinion leaders from leading academic and healthcare institutions, biomedical industry and government bodies worldwide.



DIA 2018, Boston, USA

June 24-28

The Drugs Information Association (DIA) meeting is where more than 8000 professionals in the pharmaceutical, biotechnology and medical device communities from more than 50 countries around the globe are present. CRM participated through booth exhibition to promote Malaysia's strong clinical research environment to the global audience.

### **Performance Overview**



# European Society of Cardiology Congress, Munich, Germany

August 25-29

CRM participated as a booth exhibitor in the ESC Congress which is the world's largest conference in cardiovascular medicine, reaching out to more than 30,000 healthcare professionals.



### ESMO, Munich, Germany

August 26 - 30

The European Society of Medical Oncology (ESMO) is home to all oncology stakeholders, comprising of 18,000 oncology professionals from over 150 countries. CRM participated as a booth exhibitor and has also sponsored a number of local Malaysian investigators to attend this event.

#### Other Local Events include:

- NHAM-CRM Research Track
- 3rd National Hepatitis C Symposium
- 13th Asian Clinical Oncology Society (ACOS)
- 21st Family Medicine Scientific Conference
- 12th National Conference for Clinical Research (NCCR)
- 4th National AIDS Conference
- Annual Scientific Meeting of the Malaysian Society of Gastroenterology and Hepatology (GUT) 2018
- 9th National Conference for Public Health
- 52nd Malaysia-Singapore Congress of Medicine

- 1st Ampang Medical Sub Updates
- 1st Borneo Diabetes Conference
- 6th International Postgraduate Conference on Pharmaceutical Sciences (IPOPS) 2018
- 4th International Pharmaceutical Research Conference
- 6th Malaysian Association for Cell Therapy Symposium
- Institute for Medical Research (IMR) Open Day
- World Cancer Congress, Kuala Lumpur
- International Conference on Drug Discovery on Translational Medicine

# **Highlights of 2018**

### Series of MoUs with Global Industry Players in Clinical Research

The year 2018 has seen CRM inking 6 MoUs (Memorandum of Understanding) with multiple global players in the clinical research industry:

1. The First Affiliated Hospital of Zhejiang University on the 30th January to establish a strategic partnership with one of the established medical research institute in China.



MoU signed by CEO of CRM, Dr. Akhmal Yusof and President of First Affiliated Hospital of Zhejiang University, Prof. Wang Weilin, witnessed by YBhg. Dato' Seri Dr. Chen Chaw Min, Secretary General Ministry of Health and YBhg Dato' Dr. Goh Pik Pin, Director of National Clinical Research Centre (CRC)

2. Intellim Corporation Japan, the third biggest CRO in Japan, on the 23rd March to establish strategic partnership between both companies in clinical research. The MoU leads to the 1st CRM Research Symposium in November 2018.



MoU with Intellim, Japan signed between CEO of CRM, Dr. Akhmal Yusof and President and CEO of intellim Corporation, Mr. Masakuni Ukita, and witnessed by the Ambassador of Malaysia to Japan, His Excellency Dato' Ahmad Izlan Idris

### **Highlights of 2018**

- 3. Hematogenix, a global leader in integrated laboratory services based in the United States on the 20th April 2018 to establish strategic partnerships in clinical research.
- 4. Novotech, Australia's largest independent contract research organization (CRO) on the 20th April 2018 to establish strategic partnerships in clinical research.



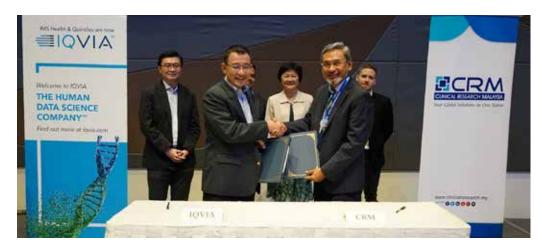
MoU signed by the CEO of CRM, Dr. Akhmal Yusof, President and CEO of Hematogenix, Dr. Hytham Al-Masri and Executive Director of Asia Operations, Novotech Dr. Yooni Kim, witnessed by the Director General of Health Malaysia, Datuk Dr. Noor Hisham Abdullah.

5. The Foundation for Innovative New Diagnostics (FIND), a Switzerland-based non-profit organization, on the 6th August. This initiative is 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 International Drug Purchasing Facility (Unitaid).



MoU signed by CEO of CRM, Dr. Akhmal Yusof and Chief Access Officer of FIND, Mr. Zachary Katz. Witnessed by the Minister of Health, YB Datuk Seri Dr. Dzulkefly Ahmad, Director General of Health, Datuk Dr. Noor Hisham, Deputy Director General of Health, YBhg. Datuk Dr. Shanaz Murad, Head of Mission and WHO representative to Malaysia, Brunei Darussalam and Singapore, Dr. Ying-Ru Jacqueline Lo, YBhg Dato Dr. Goh Pik Pin and Head of HCV & HIV Unit, FIND, Dr. Francesco Marinucci

6. IQVIA on the 28th November to establish a strategic alliance with IQVIA's global Early Phase Oncology Network (EPON). This agreement makes Clinical Research Centre at Sarawak General Hospital the first in Southeast Asia to be part of IQVIA's prestigious network of globally qualified Phase I oncology sites.



MoU signed between Dr. Akhmal Yusof and General Manager of IQVIA Malaysia, Mr. Teck Kwang Koh. Witnessed by the Director of CRC, YBhg. Dato' Dr. Goh Pik Pin, Dr. Voon Pei Jye Clinical Oncologist of Sarawak General Hospital, Mr. Desmond Dorairajoo, Head of Academic Research Group Asia Pacific IQVIA and Mr. David Horsburgh, Asia Strategy Lead, Academic Research Group Asia Pacific IQVIA.

# CRM Nurturing New Talents (NNT) in Sponsored Research Workshops

CRM has made knowledge training for investigators in Malaysia a priority and this was reflected in CRM's numerous workshops led by prominent principal investigators and representatives from the pharmaceutical industry. In the year 2018, CRM has successfully conducted a total of 6 workshops at various regions in Malaysia; Hospital Sultanah Bahiyah in Kedah, Hospital Putrajaya in Wilayah Persekutuan Putrajaya, Hospital Kuala Lumpur in Wilayah Persekutuan Kuala Lumpur, Masterclass in Cardiology at UiTM, CRM-AstraZeneca Masterclass in Oncology, and special series Oncology workshop with Dr Albiruni. These platforms provide local investigators strong insights on how to conduct clinical trials at depth and allow them to gain a better outlook on how a clinical trial journey looks like.



Datuk Dr Muhammad Radzi speaking at CRM NNT in Hospital Sultanah Bahiyah, Alor Setar

### **Highlights of 2018**



Visit to Healthcare Innoseum by KHIDI

## Visit to Top Study Sites in South Korea organized by C&R Research

On 29th July to 1st August, CRM team together with the Director-General of Health Malaysia, Datuk Dr Noor Hisham Abdullah had a series of meetings in Seoul with local Korean Sponsors and Korean Government Agencies; 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 with great help from C&R Research Inc.

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

CRM was honoured to have Dr. Albiruni Ryan Bin Abdul Razak to speak at our Nurturing New Talents in Sponsored Research workshop. Dr. Albiruni is an Assistant Professor at the University of Toronto, also a recipient of several international awards; 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. 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. Albiruni with participants of CRM's Special Series Talk



Dr. Albiruni visiting the Minister of Health



Celebrating Clinical Research through Clinical Trials Day & IKN Research Day

### Celebrating Clinical Trials Day 2018 & 2nd IKN Research Day

CRM first initiated the Clinical Trials Day back in 2017 to raise awareness on the importance of clinical trials among patients, health care professionals and the general public. Recognizing the overwhelming success of the event in the previous year, a second Clinical Trials Day was launched in September 2018 in conjunction with Institut Kanser Negara (National Cancer Institute) Research Day. 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. 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.

### Sponsorship of NPRA Officer to King's College London

Under CRM's Phase I Realization Project, CRM is committed in developing competent and qualified people with the necessary knowledge in early phase studies. On 7 September 2018, CRM sponsored Ms. Lee Wei Xin, an officer from the National Pharmaceutical Regulatory Agency (NPRA) to pursue her postgraduate studies in Master of Science in Clinical Pharmacology at King's College London, United Kingdom. As Malaysia is fervently building its capabilities in early phase clinical trials, this sponsorship marks an important step in enabling the entry and conduct of all phases of drug development in the country.



CRM's scholarship recipient, Ms. Lee Wei Xin from NPRA

### 1st International Seminar by CRM in Tokyo, Japan

Clinical Research Malaysia (CRM) held a half-day seminar on the 6th November 2018 that targets Japanese pharmaceutical and medical device companies interested in conducting clinical trials in the Asian region. This is the first time for CRM to deliver a clinical trial seminar focusing on Japan. 22 Japanese pharmaceutical



CRM seminar that was held at The Strings by InterContinental in Tokyo on 6th November 2018

companies attended the seminar that was held at The Strings by InterContinental in Tokyo. Speaking at the seminar was Datuk Dr. Shahnaz Murad (Deputy-Director of Health of Research & Technical Support, Ministry of Health Malaysia), Dr. Yoko Aoi (Principal Planning and Coordination Officer, Office of International Cooperation, PMDA, Japan) and Professor Dr. S. Fadilah (Head of Cell Therapy Centre, UKM Medical Centre). CRM provided a detailed insight into Malaysia's experience and capabilities in various types of industry-sponsored clinical trials.

# New CRM Office in KL Gateway

On the 17th December 2018, CRM has officially moved to a new office located at Menara Suezcap 1, KL Gateway, Kuala Lumpur. This move marked a significant event in CRM's history where CRM now has its own office to call home.



The team at the recent CRM National Conference 2019 overlooking CRM's new office at Menara Suezcap, KL Gateway





Visit from Japan Oncology Group (JCOG) and intellim Corporation Inc.

### **CRM Meeting with Top Japanese Oncology Group**

On the 20th December, CRM received a visit from the Japan Oncology Group (JCOG) team, accompanied by intellim Corporation Inc, Japan. JCOG is one of the top oncology research group in Japan, having conducted over 300 oncology trials in just one year. This meeting fostered a stronger relation between CRM and its Japanese counterparts.



CRM CEO, Dr Akhmal receiving the ISO Certificate from Mr Zakaria from SIRIM QAS

# ISO 9001:2015 work in 2018, Accreditation in January 2019

In effort to become a global trusted research organization, CRM has taken the initiative to be accredited with the Quality Management System ISO 9001:2015 accreditation. The year 2018 has seen all CRM staff being trained and equipped with standard operating procedures on par with the international ISO standards. The culmination of these practices was in January 2019 where CRM has officially been accredited with the ISO 9001:2015 by SIRIM QAS International.

# **Event Highlights 2018**



CRM-AstraZeneca Masterclass in Oncology, 5 March



Working visit to The Christie, Manchester, UK, 21 March



I AM AWARE Roadshow at Klinik Kesihatan Simpang Kuala, 11 April



CRM Industry Dialogue 2018/1, 2 April



NHAM-CRM Research Track 2018, 14 April



Masterclass in Cardiology, 15 May



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



Drug Information Association (DIA)
Annual Conference in Boston, 24 - 28 June



I AM AWARE mini roadshow at Hospital Queen Elizabeth II, 5 September



Visit to KBioHealth, Korea, 6 September



Signing of CRM Education
Scholarship Agreement, 7 September



Selangor Research Day 2018, 5 October



Network of Ethics Review Committees in Malaysia (NERCIM) meeting, 20 October



Perlis Research & Quality Day 2018, 30 October



2nd Visit to Japan, 2 – 8 November



REACTA Forum 2018 in Taipei, Taiwan, 9 November



CRM Training Programme - Fundamental of Clinical Research & Practice Course Module 1, 16 April



IQVIA Prime Site JSC Meeting, 12 April



I AM AWARE Roadshow at Hospital Tuanku Fauziah in Kangar, Perlis, 10 April



Samsung Bioepis Korea Visit, 2 May



I AM Aware Roadshow at Klinik Kesihatan Greentown in Ipoh, 2 May



1st Borneo Diabetes Conference 2018, Miri, Sarawak, 13 - 15 July



Nurturing New Talents in Sponsored Research, Hospital Putrajaya, 25 July



CRM Meetings in Seoul, Korea, 29 July - 1 August



National Conference for Clinical Research 2018, 24 September



Investigator Dialogue 2018, 26 September



CRM Industry Dialogue 2018/2, 17 October



European Society for Medical Oncology (ESMO) 2018 Congress, Germany, 19 – 23 October



World Innovation Summit for Health (WISH) 2018, Doha, 13 November



Nurturing New Talents in Sponsored Research at Institut Pediatrik, Hospital Kuala Lumpur, 14 December

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Moving forward in 2019, CRM will remain focused on the Phase 1 Realization Project (P1RP) where we will drive stronger efforts to bring in more Phase 1 clinical trials to Malaysia. Various workshops will be conducted throughout the year with prominent figures in the Phase 1 environment taking the lead to guide Principal Investigators with the relevant skills. In light of CRM's recent accreditation of Quality Management System ISO 9001:2015, CRM will continue to provide our stakeholders with the highest standards of service by implementing the practice of the ISO standards. CRM will also remain steadfast in our 5 key strategies and we are anticipating to conduct our First in Human trial in 2019.







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