

ANNUAL 2017

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INTRODUCTION

Clinical Research Malaysia's 2017 Annual Report

Clinical Research Malaysia is pleased to share our achievements of the past year's successes in this 2017 Annual Report. We encourage our stakeholders, industry partners, investigators and other 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 an ISR 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 industry sponsored research (ISR).

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.

As icing on the cake, 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 2017, Malaysia was awarded, for the third consecutive year, as the top four best healthcare provider in the world by International Living-Annual Global Retirement Index.

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 Clinical Research Malaysia (CRM). 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, CRM works together with its partners to create an impetus in delivering better services to its end clients, while at the same time creating high skilled job opportunities.

We hope that through this annual report we will continue to highlight CRM's milestone to showcase Malaysia's potential as the preferred hub for conducting clinical trials.



FOREWORD BY CEO

Ladies & Gentlemen, may I present the 2017 Annual Report of Clinical Research Malaysia (CRM).

CRM was founded with the vision in making Malaysia the preferred destination for Industry Sponsored Research (ISR). Since 2015, we have formulated and adopted 5 key strategies which are to grow the principal investigators and sites, grow the number of ISRs, collaborate with stakeholders, create awareness of CRM and develop our human capital. These, together with four of our business core values (transparency, honesty, accountability and trustworthiness) are the basis to ensure the continuous success of CRM.

Having said this, 2017 has truly been a landmark year of achievements for both CRM and Malaysia in the field of clinical research. To start with, we have surpassed two out of the three Key Performance Indicator (KPI) set in the Entry Point Project 2 (EPP2) of the National Key Economic Area (NKEA). This spells great confidence by global pharmaceuticals in making Malaysia the go-to destination for clinical research. My sincere gratitude to all 151 CRM personnel nationwide whose commitment and hard work have made all this possible. In addition, we witnessed the successful launching of the Phase 1 Clinical Trial Guidelines, the first of such in Malaysia and a milestone achievement in the Phase 1 Realisation Project (P1RP) which was initiated in May 2016.

We have also focused much efforts in patient engagement/ public awareness activity with the 'I Am AWARE' roadshows which took place throughout the country. The results saw successful registration of over 3000 patients/volunteers. This was culminated with the nation's premier launch of the Clinical Trials Day at the National Cancer Institute, Putrajaya in May 2017 as a tribute to all those who have contributed in clinical research.

I would like to thank all members of CRM's Board of Directors chaired by the Honourable Datuk Seri Dr. S. Subramaniam, Minister of Health Malaysia, for their support and guidance. My heartfelt gratitude also goes to our stakeholders which comprise of sponsors, contract research organizations, academia, institutions, investigators, clinical research personnel and all those who have directly or indirectly contributed to the conduct of ISR 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.

I hope that you enjoy reading it.

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. There are no changes to this lineup of BOD since 2016.



Y. B. Datuk Seri Dr. S. Subramaniam 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. Datuk Dr. Shahnaz Murad
Deputy Director General of Health (Research & Technical Support)



Y. B. Senator Datuk Prof Dr. Sim Kui Hian Senior Consultant Cardiologist, Sarawak General Hospital Heart Centre



Y. Brs. Dr. Goh Pik Pin Director, National Clinical Research Centre, Malaysia



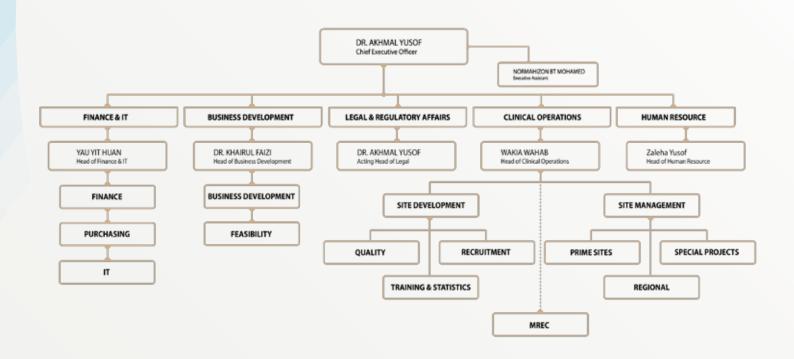
Y. Bhg. Prof. Datuk Dr. Adeeba Binti Kamarulzaman Dean of the Medical Faculty at Universiti Malaya



Mr Ewe Kheng HuatExecutive Director of the Pharmaceutical Association of Malaysia



ORGANIZATIONAL CHART





CORE SERVICES, VALUES AND KEY STRATEGIES

CRM's Core Services

- Complimentary feasibility services
- Development & placement of study coordinators
- Review of clinical trial agreements (CTAs) & non-disclosure agreements (NDAs)
- Clinical trial budget management
- Archiving

Our Core Values





We practice transparency and openness in all our operations, including financial processes and budget management.



We aspire to be honest with one another, our clients and our business partners.







We set a high performance expectations and hold ourselves responsible for the quality of our work and the results we achieve as individual, as a team and as a company.



We adhere to the highest standards of professionalism and integrity and uphold the faith and confidence our clients have placed in us.



Our 5 Key Strategies



02

GROW

ISR

COLLABORATE

04

05

WITH STAKEHOLDERS CREATE AWARENESS OF CRM DEVELOP HUMAN CAPITAL



2017 HIGHLIGHTS

MOU with C&R Research Inc.

CRM has sealed a partnership with C&R Research Inc, Korea's largest contract research organization, to cooperate in promoting clinical trial activities in Malaysia and South Korea. The signing of the Memorandum of Understanding which took place in January 2017 spells out for both parties to provide support and valuable resources to complement the needs of each country in terms of business development, clinical trial operations and trainings. Malaysia stands to benefit through business networking opportunities from South Korea pharmaceutical and biotechnology companies which may see more trial coming into the country. On the other hand, C&R Research Inc. will enjoy CRM's complementary feasibility services and support in clinical projects as well as in C&R's establishment in Malaysia.



Figure 1. MoU Signing between CRM and C&R Research Inc.

Clinical Trials Day 2017

CRM initiated the 2017 Clinical Trials Day to raise awareness on the importance of clinical trials among patients, health care professionals and the general public. The event which was a first of its kind in the country, was organized by CRM in collaboration with the National Cancer Institute and the Clinical Research Centre (CRC). The event pulled together medical professionals who are involved in clinical research, patients, experts from the industry, academia as well as patient support group under one roof. The launching of the Clinical Trials Day was officiated by the Minister of Health, Datuk Seri Dr. S. Subramaniam, and witnessed by the Secretary General of the Ministry of Health, Datuk Dr. Chen Chaw Min and the Deputy Director-General of Health (Research & Technical Support), Datuk Dr. Shahnaz Murad.

2017 HIGHLIGHTS



Figure 2. Launching of the Clinical Trials Day by Health Minister, Datuk Seri Dr. S. Subramaniam

I AM AWARE Roadshows

As a run up to the Clinical Trials Day, a series of 'I AM AWARE' roadshows were also held at Ministry of Health hospitals across the nation. These campaigns have enabled CRM to register more than 3,000 patients and healthy volunteers who have shown interest in clinical trials. The roadshows are part of CRM's ongoing efforts in enhancing the current clinical research ecosystem in Malaysia by ensuring a robust pool of patients and volunteers for trials, while at the same time continuously investing in the infrastructure of qualified personnel, state-of-the-art clinical trial sites and stringent regulatory reviews.



Figure 3. I AM AWARE Roadshow in 2017



2017 HIGHLIGHTS

Sponsorship of Officers from the National Pharmaceutical Regulatory Agency to Manchester University

Under CRM's Phase I Realization Project, CRM is committed in developing competent and qualified people with the necessary knowledge in early phase studies. In August 2017, CRM sponsored two regulatory officers from the National Pharmaceutical Regulatory Agency to pursue their postgraduate studies at Manchester University, United Kingdom. During the course, they will work within a leading Phase I cancer clinical trial unit and learn details of designing, delivering Phase I clinical studies, as well as understanding requirements of pre-clinical data. As Malaysia is in the midst of 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.



Figure 4. CRM's scholarship recipients from the National Pharmaceutical Regulatory Agency

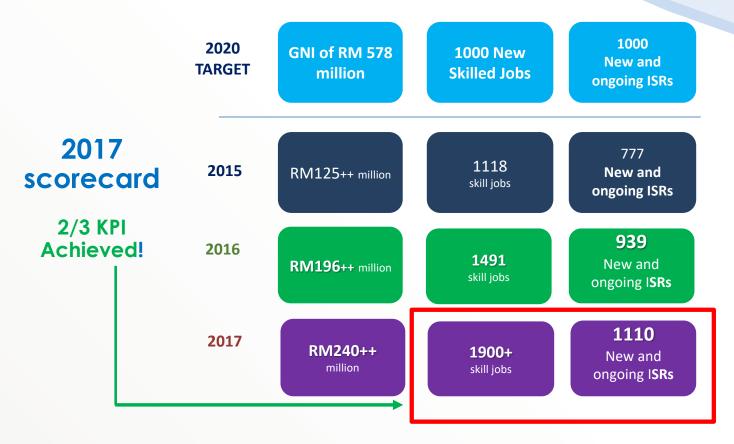


Figure 5. Launching of the Malaysian Phase I Clinical Trial Guidelines

Launching of the Malaysian Phase I Clinical Trial Guidelines

The development of the Malaysian Phase I Clinical Trial Guidelines marks an important milestone in the history of clinical research in Malaysia. The guidelines are part of a much bigger initiative of the Phase I Realization Project that aims at establishing and growing an early phase research industry in Malaysia. The guidelines were developed based on the Association of British Pharmaceutical Industry Guidelines for the conduct of Phase I trials. Taking into consideration the local regulatory bodies and agencies' existing procedures, and the local clinical trial environment, adaptation of relevant areas has been done to facilitate the applicability of these guidelines in Malaysia. The guidelines was launched by Dr. Goh Pik Pin, Director of the National Clinical Research Centre during CRM's Industry Dialogue 2017.





CRM's vision by 2020 is to attract 1000 new and ongoing industry sponsored research (ISR), achieve a gross national income (GNI) of RM578 million and develop 1000 high skilled jobs in the clinical research industry. In 2017, the recorded GNI totalled over RM 240 million, an increase of RM 44 million from 2016, while the number of skill jobs in clinical research has grown by 28% to a total of 1911 from the previous year.

CRM also constantly compiles and tracks the number of ISRs 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 a decline in the number of ISRs in 2016, a slight increase of 5.6% was observed in 2017 (Figure 6).

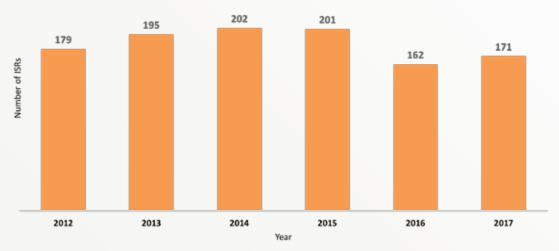


Figure 6: Number of Industry Sponsored Research from 2012–2017



The number of ISRs conducted at Ministry of Health (MOH) sites have seen a healthy growth in 2017 in comparison to the previous year. In 2017, a total of 110 MOH hospitals and health clinics was reported to have conducted industry sponsored research, up from 94 in 2016 (Figure 7).

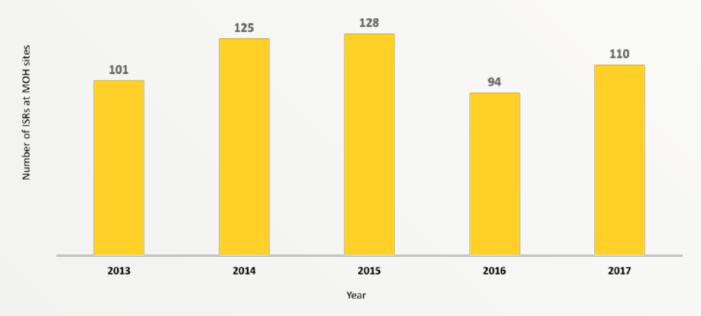


Figure 7: Number of ISRs conducted at Ministry of Health Hospitals from 2013–2017

Types of Clinical Trials

Interventional trials accounted for the largest proportion of trials in Malaysia in 2017, with Phase III trials recording the highest number of trials followed by bioequivalence studies, phase II, phase IV, phase I and pre-clinical studies (Figure 8).

Out of all interventional trials, 72 trials or 49.7% involved new investigational products, 51 (35%) were bioequivalence studies and 18 (12%) were medical device trials. New investigational products are generally comprised of drugs, biologics, biosimilars or supplements (Figure 9).

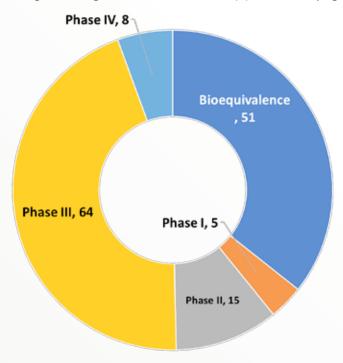


Figure 8. Breakdown of Interventional studies according to phases (n=144)

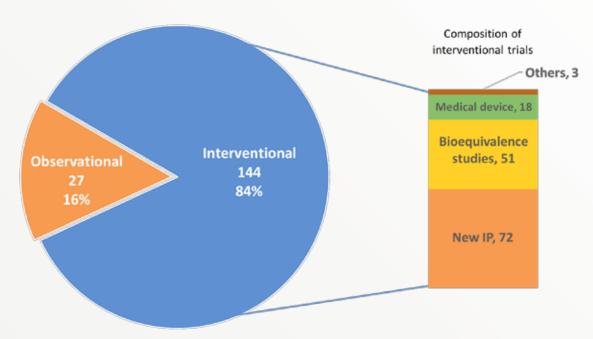


Figure 9. Classifications of clinical trials conducted in Malaysia in 2017



Disease patterns in Malaysia are almost similar to 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 2017, cardiovascular trials accounted for the highest number of trials followed by oncology trials (Figure 10), a pattern which is similarly seen in the previous years. However, endocrinology trials have taken a dip and recorded only 1 trial in 2017 as compared to 10 trials in 2016. Gastroenterology/ hepatology trials which recorded the third highest number of trials in 2017 had 15 trials compared to only 6 the year before.

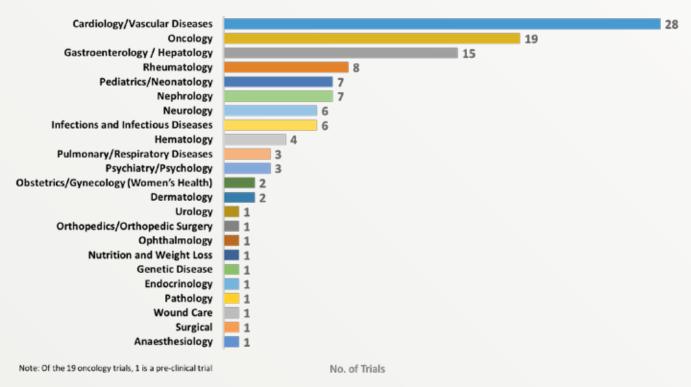
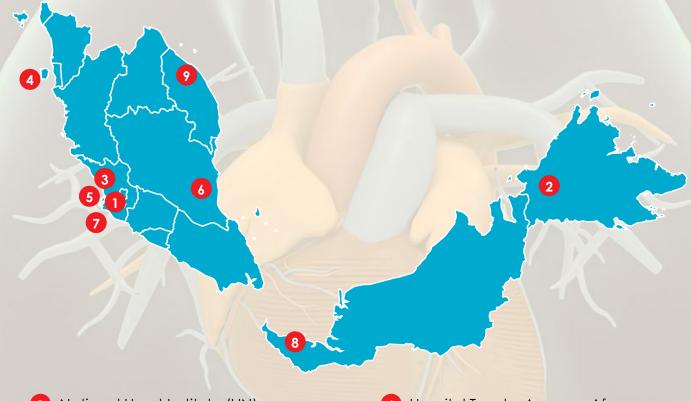


Figure 10. The therapeutic areas of clinical trials conducted in Malaysia

Active Sites in Cardiology, Oncology and Gastroenterology/ Hepatology Clinical Trials in 2017

Below are the sites which have conducted newly registered cardiology, oncology and gastroenterology/hepatology trials in 2017. Besides these sites, there are also other sites with experience in these respective therapeutic areas prior to 2017. These sites are listed below each map. 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.

Active Sites Conducting Cardiology Clinical Trials in 2017



- 1 National Heart Institute (IJN)
- 2 Hospital Queen Elizabeth II
- 3 Hospital Serdang
- 4 Hospital Pulau Pinang
- 5 Pusat Perubatan Universiti Malaya (PPUM)
- 6 Hospital Tengku Ampuan Afzan
- 7 Hospital Kuala Lumpur
- 8 Pusat Jantung Sarawak
- 🤈 Hospital Raja Perempuan Zainab II

Other sites with experience in cardiology trials:

- Hospital Sultanah Bahiyah
- Hospital Sultanah Nur Zahirah
- Hospital Sultanah Aminah
- Hospital Universiti Sains Malaysia (HUSM)
- Pusat Perubatan Universiti Kebangsaan Malaysia (PPUKM)
- Universiti Teknology Mara (UiTM)



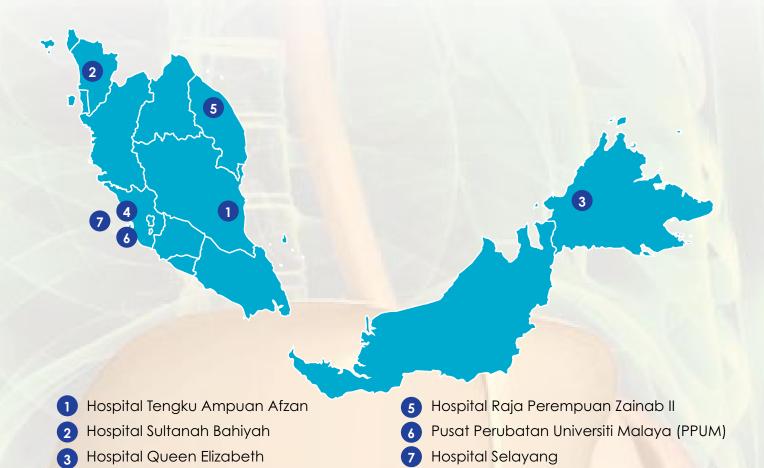
Active Sites Conducting Oncology Clinical Trials in 2017



Other sites with experience in oncology trials:

- Pusat Perubatan Universiti Kebangsaan Malaysia (PPUKM)
- Hospital Sultanah Bahiyah
- Gleneagles Medical Centre Penang
- Mount Miriam Cancer Hospital
- Hospital Raja Permaisuri Bainun
- Hospital Melaka
- Subang Jaya Medical Centre
- Mahkota Medical Centre
- Hospital Sultan Ismail
- Hospital Raja Perempuan Zainab II
- Hospital Sultanah Nur Zahirah
- Hospital Queen Elizabeth

Active Sites Conducting Gastroenterology/Hepatology Clinical Trials in 2017



Other sites with experience in gastroenterology/hepatology trials:

- Pusat Perubatan Universiti Kebangsaan Malaysia (PPUKM)
- Hospital Pulau Pinang

4 Hospital Ampang

- Hospital Sultanah Aminah

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 feasibility received from 2015 to 2017 recorded a steady growth from 80 in to 2015 to 132 in 2017 (Figure 12). Most feasibility studies received in 2017 were studies in oncology followed by gastroenterology, paediatrics, haematology and infectious diseases (Figure 13).

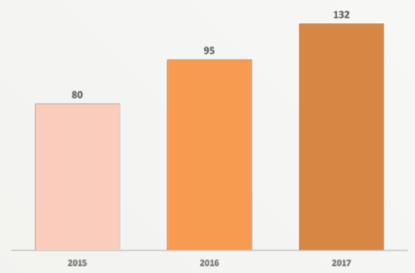


Figure 12. Full feasibilities received from 2015 to 2017

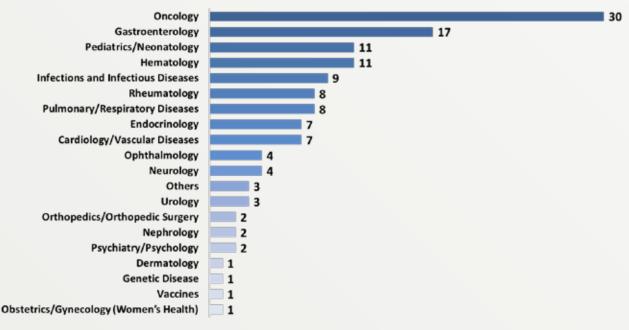


Figure 13: Full feasibilities received in 2017 by therapeutic area (n=132)



Table 1 shows the top 5 indications of the 5 highest therapeutic areas of feasibility received from 2015 to 2017. Ulcerative colitis & Crohn's disease (20), non-small cell lung cancer (15) and breast cancer (9) received the highest feasibility studies received by CRM during this time period.

Table 1. Top indications from the five highest feasibilities by therapeutic area received from 2015 to 2017

Top 5 full feasibilities received from 2015–2017 by therapeutic area	Top 5 indications
Oncology	Non-small cell lung cancer Breast cancer Gastric/gastroesophageal junction carcinoma Colorectal cancer Liver cancer
Gastroenterology	Ulcerative colitis & Crohn's disease Hepatitis B Nonalcoholic steatohepatitis Diabetic gastroparesis Duodenal ulcer and gastric ulcer
Paediatrics/Neonatalogy	Paediatric Respiratory Syncytial Virus Type 2 diabetes mellitus (in paediatric population) Growth hormone deficiency Attention deficit hyperactivity disorder Haemophilia B
Haematology	Acute myeloid leukemia Haemophilia Thalassemia Non-hodgkins lymphoma T cell lymphoma
Infectious disease	Influenza A Ventilator Acquired Pneumonia Pneumonia HIV Carbapenem Resistant Organisms

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.



29th Annual Euromeeting, Glasgow *March* 29 – 31

CRM participated in this event through booth exhibition and poster presentation, reaching out to nearly 2,500 delegates from in and outside of Europe.



DIA 2017, Chicago, IL

June 18 – 22

CRM participated through booth exhibition as well as presented a poster to more than 8000 professionals in the pharmaceutical, biotechnology and medical device communities from more than 50 countries around the globe.



European Society of Cardiology Congress, Barcelona

August 26 – 30

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, Madrid

September 8 – 12

CRM participated as a booth exhibitor in the European Society of Medical Oncology (ESMO) which is home to all oncology stakeholders, comprising 18,000 oncology professionals from over 150 countries.



BioJapan, Pacifico, Yokohama, Japan

October 11 - 13

CRM's participation as a booth exhibitor at BioJapan is seen as an important step in interacting with the Japanese pharmaceutical industry to stimulate new business opportunities in clinical research.

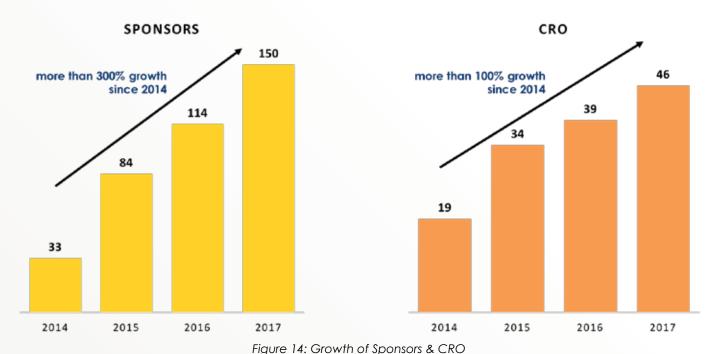
Other Local Events include:

- NHAM-CRM Research Track
- National Conference for Clinical Research (NCCR)
- International Medical Device and Technology Conference
- 18th Congress of Asian Society for Vascular Surgery
- 12th MOH ASM Scientific Meeting
- College of Physicians Annual Scientific Meeting
- Malaysian Thoracic Society Annual Congress
- Family Medicine Society Conference
- MyNEURO 2017
- National Dengue and Arbovirus Conference



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 2017, 150 sponsors and 46 CROs utilized CRM's services. This can be translated to a growth of more than 300% in sponsors and more than 100% in CROs since 2014 (Figure 14).



Growth of CRM Study Coordinators

Due to the rise in the number of ISRs in 2017, the number of study coordinators increased in tandem. In its infancy in 2012, CRM had 22 study coordinators that were placed throughout Malaysia at various sites conducting ISR and this number has grown to 113 in 2017 (Figure 15). 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 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.

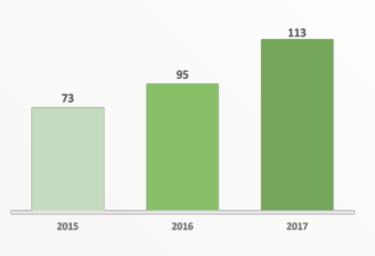


Figure 15: Growth of Study Coordinators at CRM



CRM IN PHOTOS



A Dialogue Session with the DG of Health Malaysia inLondon, UK, 20 Aug



ESC Congress Barcelona 2017, 26-30 Aug



Scholarship Agreement Signing between CRM, MOH & NPRA Officers, 28 Aug



IMEDITEC 2017, 6-7 Sept



CRM visit The Christie, UK, 7 Sept



Meeting with China Medical University Hospital, 30 Aug



ESMO Congress 2017 | Madrid, Spain, 8-12 Sept



CRM visit Hematogenix Laboratory, Alderley Park, UK, 7 Sept



5th Asia Pacific Conference on Public Health, 10-13 Sept



Sabah Research Day 2017, 13 Sept



Visit to Prince Margeret Hospital in Toronto, Canada, 14 Sept



Meeting with MATRADE, 15 Sept



Meeting with delegates from South Korea, 15 Sept



Steering Committee Meeting on the Hep C Program, 20 Sept



I AM AWARE Roadshow in Hosp. Queen Elizabeth, Kota Kinabalu, 25 Sept



Meeting with FARMASIA Sdn.Bhd., 25 Sept



Meeting with Naluri Hidup Sdn. Bhd., 25 Sept



intellim Corporation visit to Malaysia, 26 Sept



NCCR + REACTA Forum 2017, 27-29 Sept



MoU Signing between CRM & Taipei Medical University, 29 Sept



CRM IN PHOTOS



Negeri Sembilan Research Day 2017, 5 Oct



Visit to intellim Corporation, Japan, 10 Oct



I AM AWARE Roadshow in Hospital Tuanku Ja'afar, 10 Oct



I AM AWARE Roadshow in Hospital Melaka, 11 Oct



I AM AWARE Campus Roadshow in IMU, 13 - 14 Oct.jpg





Visit to CROèe, Japan, 10 Oct



Meeting with A-Bio Sdn Bhd, 17 Oct



11 - 13 Oct

MoU Signing between CRM and IMU, 23 Oct



25 Oct



18th Congress of Asian Society for Vascular Surgery, 26 Oct



12th MOH-AAM Scientific Meeting 2017, 30 Oct



2 Nov



CRM 2nd Board Meeting for 2017, 1 Nov



College of Physicians, AMM Annual Scientific Meeting, 9 - 12 Nov



Malaysian Phase I Clinical Trial

Meeting with Hematogenix Lab, 16 Nov



CRM, CRC & IQVIA Prime Sites Network 2nd JSC Meeting for 2017, 15 Nov



Meeting & Visit with Dr Albiruni Ryan Abdul Razak, 27 Nov

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WHAT IS NEXT IN 2018

Moving forward in 2018, CRM will be embarking on efforts to build a globally trusted organization by working towards ISO 9001:2015 certification. Various trainings will be conducted in order to equip CRM's workforce with the necessary knowledge and skills to achieve this tall order of receiving this certification by 2019. CRM will also be taking up the Malaysian Anti-Corruption Commission (MACC) oath of anti-corruption, in line with our core values of transparency, honesty, accountability and trustworthiness.





Speed I Reliability I Quality





Your Global Solutions in One Nation

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