CRM

CLINICAL RESEARCH MALAYSIA

Your Global Solutions in One Nation

ANNUAL REPORT

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FOREWORD BY CEO

May I present to you the 2016 Annual Report of Clinical Research Malaysia (CRM).

Trustworthiness, honesty, accountability and transparency are the core values of our business which we practice to encourage the growth of Industry Sponsored Research (ISR) in Malaysia. My gratitude goes to the more than 144 CRM staff nationwide for their dedication and hardwork which has enabled us to meet our yearly targets. CRM's five key strategies will be our core backbone as we continue to focus our efforts in making Malaysia the preferred destination for ISR.

2016 was a year with various collaborations, meetings and conferences which saw Clinical Research Malaysia's (CRM) network extending beyond the region. I am glad we have accomplished so much. CRM will continue to be committed to provide its services including the feasibility service which will remain as complimentary to sponsors and contract research organization (CROs), hence, bringing more industry sponsored research (ISR) to Malaysia.

This year marked the first ever growth on the number of new clinical investigators since 2008. We have recorded 184 new clinical investigators in 2016 more than doubled the figure in 2015 as recorded in the National Medical Research Registry (NMRR). The number of skilled jobs created in the clinical research industry has grown from 1118 in 2015 to 1491 in 2016 with a 33% growth. CRM has increased its manpower (mainly study coordinators) by 30% to support investigators in the conduct of clinical trials. This, subsequently, creates career opportunities for doctors, nurses, medical assistants and biomedical graduates. 162 new ISRs were recorded versus the target of 155 (4% above target), which means that CRM has achieved our KPI 1 for 2016.

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 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 everyone who took the time to contribute their valuable input to the report. I hope that you enjoy reading it.

Dr. Akhmal Yusof
CEO
Clinical Research Malaysia

INTRODUCTION

Clinical Research Malaysia's 2016 Annual Report

Clinical Research Malaysia is pleased to share our achievements of the past year's successes in this 2016 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.

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.

YB 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)

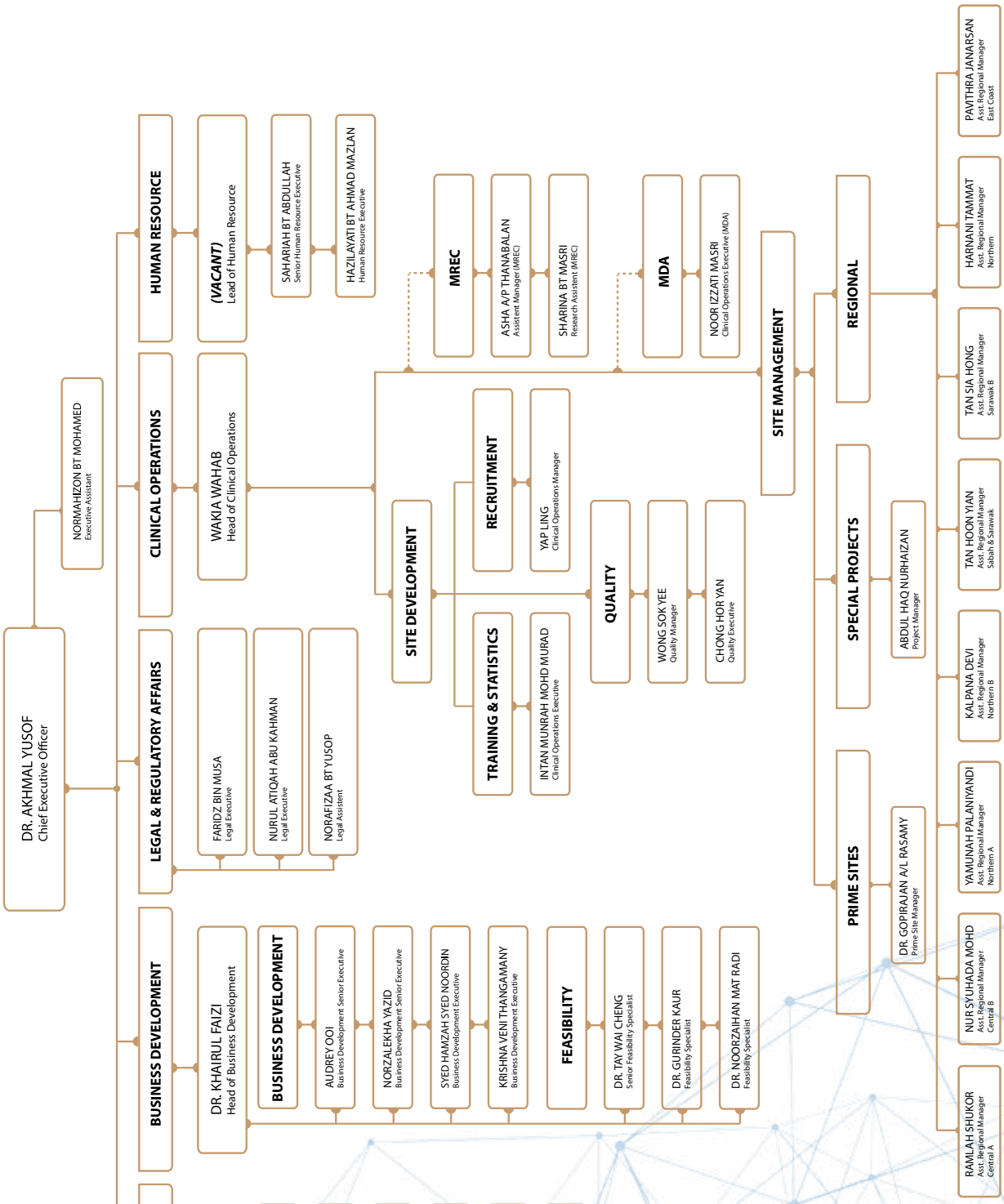
YB Senator Datuk Prof Dr. Sim Kui Hian
Senior Consultant Cardiologist, Sarawak General Hospital Heart Centre

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

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

Prof Dr Adeeba Binti Kamarulzaman
Dean of the Medical Faculty at Universiti Malaya

ORGANIZATIONAL CHART



CORE SERVICES, VALUES AND KEY STRATEGIES

CRM's Core Services

- Complimentary feasibility service
- Development & placement of study coordinators
- Review of clinical trial agreements (CTAs) & non-disclosure agreements (NDAs)
- Clinical Trial Budget Management
- Archiving

Our Core Values

Transparency

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

Honesty

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

Accountability

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.

Trustworthiness

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

PERFORMANCE OVERVIEW

Industry Sponsored Research in Malaysia

VISION

2020

To establish Malaysia as a Preferred Destination for Industry Sponsored Research (ISR)

1000 ISR	GNI RM 578	1000
New & Ongoing Trials	Million	New High Skill Jobs

CRM's vision by 2020 is to create 1000 new and ongoing industry sponsored research (ISR), achieve a gross national income (GNI) of 578 million and 1000 high skill jobs in the clinical research industry. In 2016, the recorded GNI totalled over RM 196 million, an increase of RM 71 million from 2015, while the number of skill jobs in clinical research has grown by 30%.

Lower Number of ISR Due to Global Decline

CRM is entrusted to compile and track the number of ISRs in Malaysia from the Medical Research and Ethics Committee (MREC) and all Institutional Review Boards/ Independent Ethics Committees (IRB/IECs) and these numbers are reported annually to the Malaysian government. Between 2012 and 2015, Malaysia has seen a steady increase in the number of Industry Sponsored Research (ISR) from 179 trials to 201 trials. From 2014 onwards, there was a global decline (by 10%) in the number of ISR recorded and this was reflected in the lower number of ISRs coming into Malaysia during this time period (Figure 1).

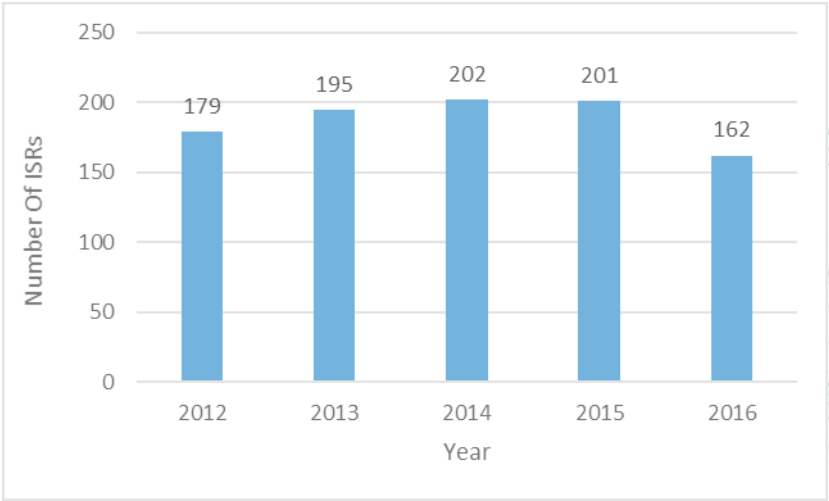


Figure 1: Number of Industry Sponsored Research from 2012–2016

PERFORMANCE OVERVIEW

The number of ISRs conducted at Ministry of Health Hospitals have seen a rise from 2013 onwards. However, due to the global decline in ISRs, the number of trials conducted at these sites in 2016 has seen a decline (Figure 2).

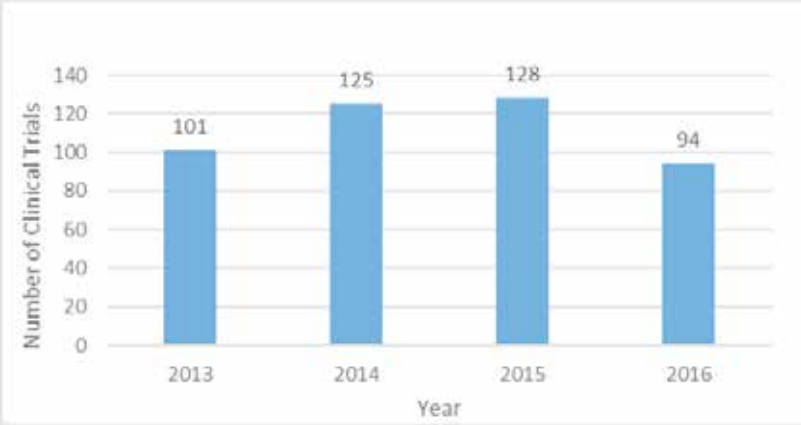


Figure 2: Number of ISRs conducted at Ministry of Health Hospitals from 2013–2016

Types of Clinical Trials

Interventional trials comprise most of the ISRs conducted in 2016 and most of the trials involved drugs/investigational medical device (Figure 3). The majority of the trials were Bioavailability/ Bioequivalence (BABE) studies, followed by Phase 3 and Phase 4 trials.

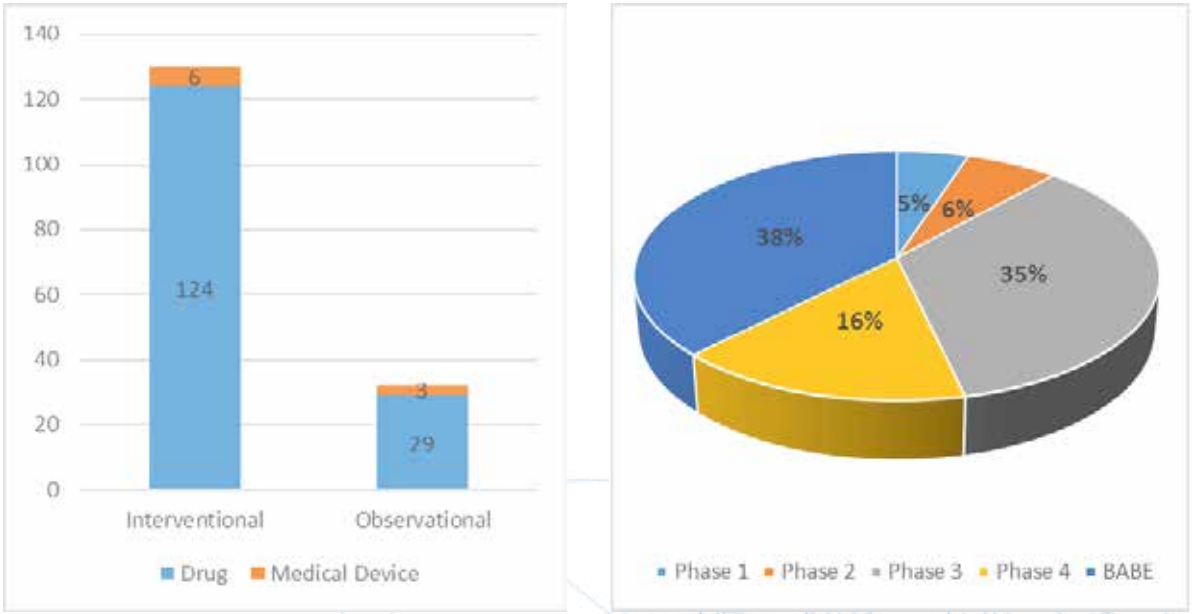


Figure 3. Classifications of clinical trials conducted in Malaysia

ISR Distribution According to States in 2016

From the ISR distribution across the states, Sarawak had the highest number of ISRs conducted in Malaysia, followed by Selangor and Penang (Figure 4).

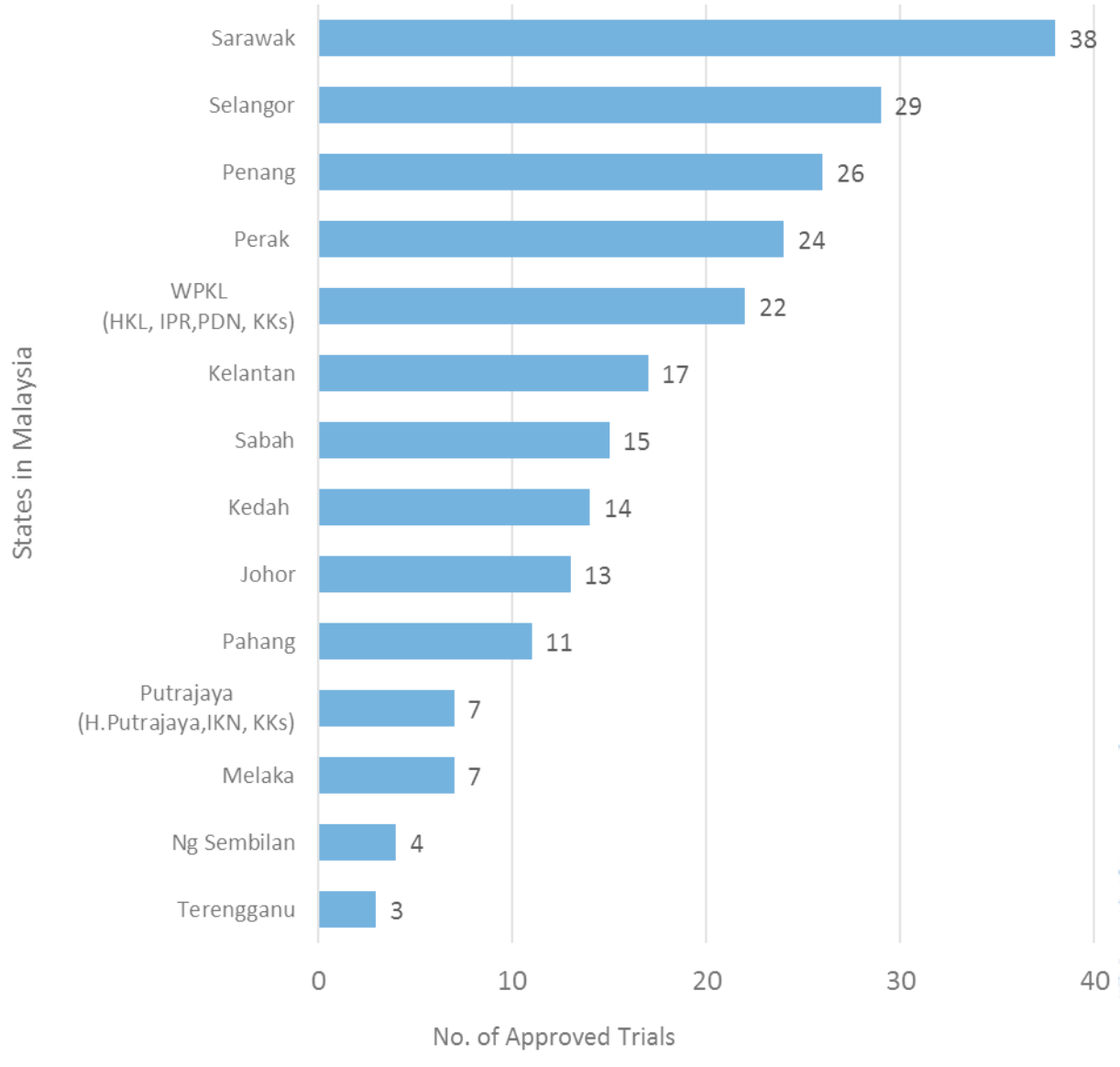


Figure 4. ISRs conducted at Ministry of Health Hospitals at the various states in Malaysia

Types of ISR According to Therapeutic Areas

Disease patterns in Malaysia are like those in Western countries and Malaysia patients have similar unmet medical needs that Western countries have. Cardiovascular disease, diabetes and cancer are the major cause of mortality and morbidity in Malaysia. The high incidence of these chronic diseases ensures large and relevant patient populations. In 2016, cardiovascular trials accounted for the highest number of trials followed by oncology and endocrinology trials (Figure 5).

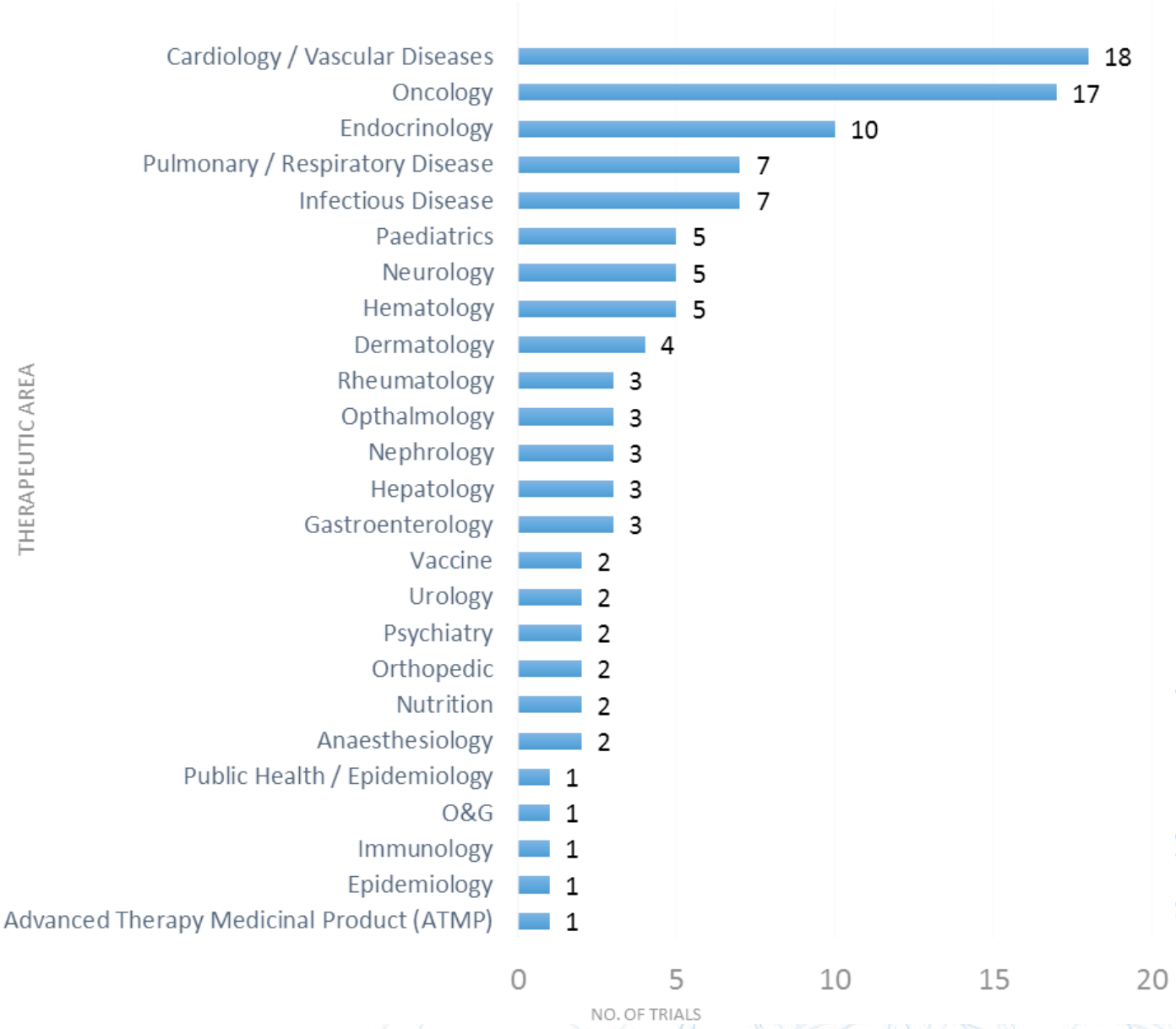


Figure 5. The therapeutic areas of clinical trials conducted in Malaysia

PERFORMANCE OVERVIEW

Double Digit Growth in Sponsors & CROs

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 2016, 114 sponsors and 39 CROs utilized CRM's services, a growth of 36% and 15% respectively from the previous year (Figure 6).

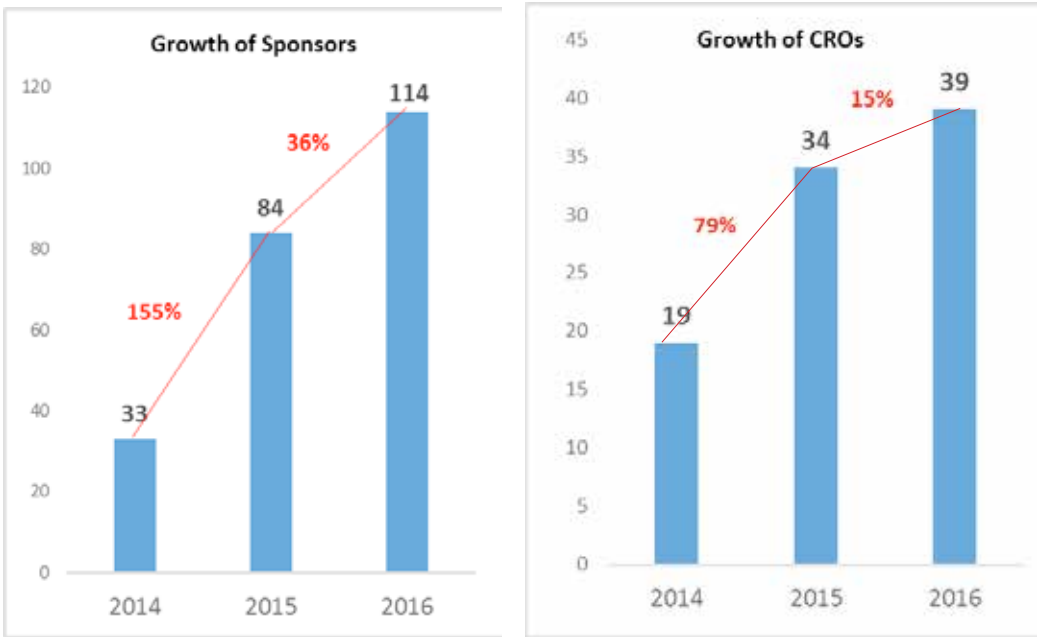


Figure 6: Growth of Sponsors & CRO

Growing Number of Study Coordinators Due to Positive Demand

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 95 study coordinators in 2016 (Figure 7). CRM has expanded its operations beyond the realm of Ministry of Health sites. It has 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 7: Growth of Study Coordinators at CRM

First Growth in the Number of Principle Investigator in Almost a Decade

Principal investigators (PIs) are the main drivers in Industry Sponsored research. Their roles and contribution in ISR is important in attracting more clinical trials to Malaysia. There was a growth in the number of PIs in 2016 (Figure 8) after the country recorded a sharp decline in 2015. One of the reasons for the decline was due to senior investigators leaving their services because of retirement with many of them not having put in place proper succession planning. Additionally, there was lack of support in promoting ISRs to junior doctors during that time.

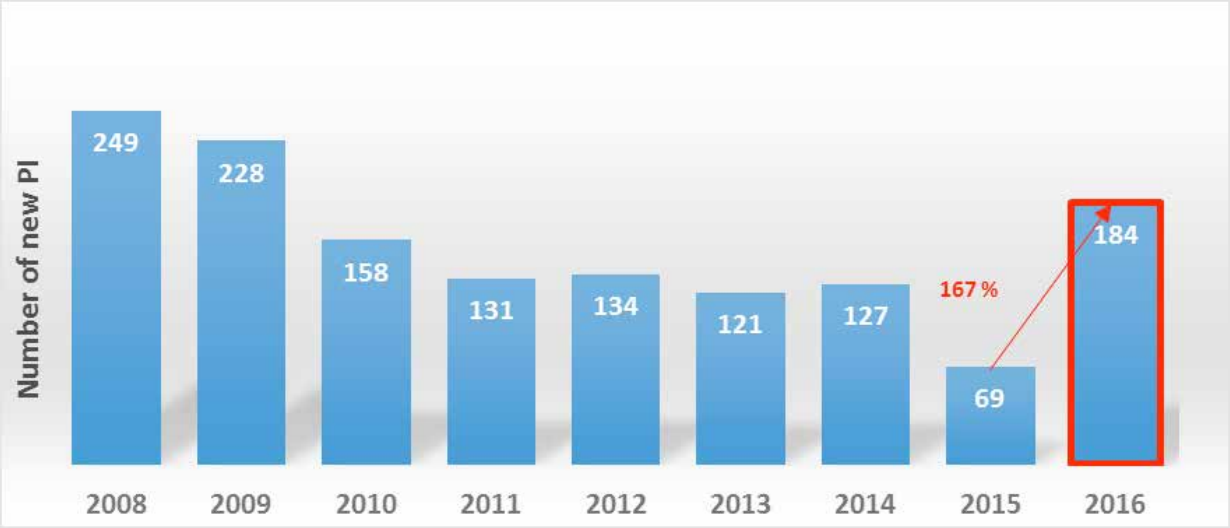


Figure 8: Growth of Principal Investigators in Malaysia

With the formulation of CRM's five strategies in 2015, CRM took up several initiatives to increase the number of investigators. One of the initiatives is by supporting most of the State Research Days that were conducted nationwide during that year, and this saw an impressive 550 abstracts submitted from all over the country. Seeing its success, CRM has committed to support more State Research Days in 2016. State Research Day is a Ministry of Health initiative which is organized nationwide annually. Its aim is to provide an avenue and opportunity to the allied health and medical personnel to share their research findings, besides providing recognition and encouragement for them to engage in research. It is also a platform to raise awareness on the importance of research in improving patient care in the country.

Kuala Lumpur Hospital Research Day

Growth in Feasibilities Indicating Global Interest in Malaysia

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 in Malaysia but it is also a method to promote that possibility to sponsors and CROs who may not be familiar with Malaysia's capabilities.

CRM's feasibility study 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 2013 to 2016 recorded a steady growth within this time period (Figure 9). Majority of the feasibility studies received in 2016 were oncology studies, followed by haematology and gastroenterology.

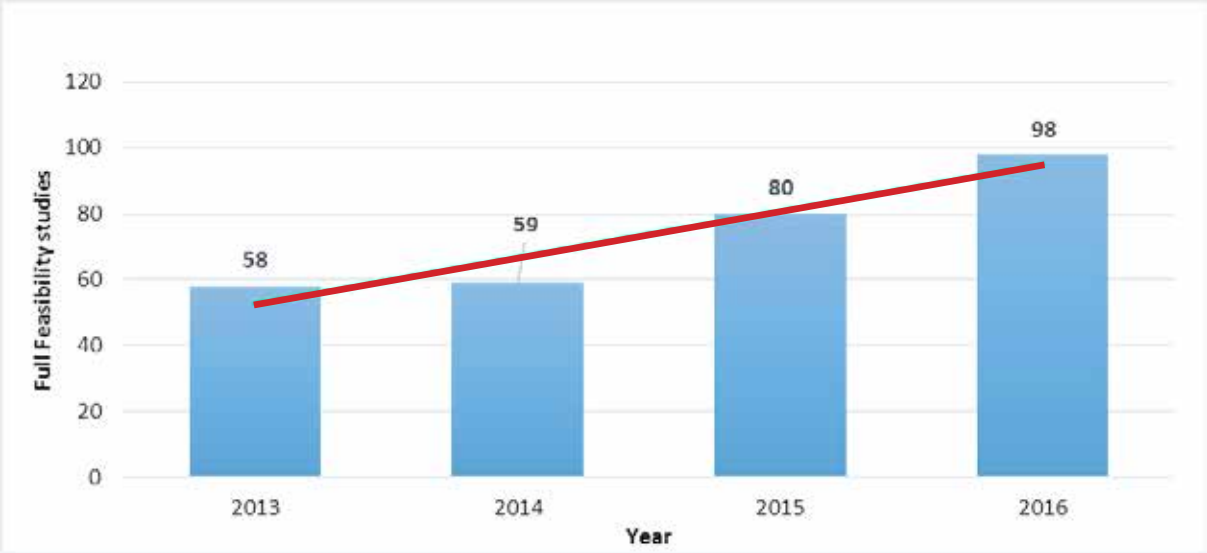


Figure 9: Growth of Full Feasibility Studies

PROMOTIONAL ACTIVITIES

Flying the Malaysian Flag High with Increased Activities

CRM was involved in about 368 activities in 2016, a slight increase as compared to the year before (Table 1). Meetings with the clinical research industry players (Table 2) comprises the largest percentage of CRM activities and these include meetings with the pharmaceutical and contract research organizations, organizing dialogue sessions, participation in conferences and exhibitions (both locally and abroad) as well as talks at seminar at hospitals and universities.

Table 1. Overall activities and promotion by CRM in 2015 vs 2015

Year	Activities and Promotions
2015	344
2016	368

Industry Dialogue 2016

Table 2. CRM's involvement in various activities and promotion in 2015 & 2016

Activities	2015	2016
International missions	4	6
Hospital level meetings and speaking engagements	63	76
Meetings with the industry	114	202
University level meetings and speaking engagements	17	17
Meetings at MOH	56	67

NATIONAL AND INTERNATIONAL MISSIONS

Biopharma Asia, Singapore

13th MSH Annual Scientific Meeting

DIA Japan 2016

NHAM Annual Scientific Meeting 2016

AstraZeneca National Oncology Summit 2016

DIA China 2016

2016 HIGHLIGHTS

MOU with DNDi

CRM has collaborated with The Drugs for Neglected Diseases *initiative* (DNDi) which is a patient-needs driven, not-for-profit research and development (R&D) organization that develops safe, effective, and affordable medicines for neglected diseases that afflict millions of the world's poorest people.

This is an initiative to come out with new treatment regiments for Hepatitis C with the overall objective of ensuring equitable access to affordable and effective treatments for patients suffering from this disease in Malaysia.

Memorandum of Understanding between CRM and DNDi

MOU with Aurigene Discovery Technologies & Institute for Medical Research

An MOU between Aurigene Discovery Technologies (M) Sdn Bhd and the Institute for Medical Research was signed for the development of Aurigene's novel anti-cancer compounds and associated biomarkers. This is CRM's first involvement in a pre-clinical study where CRM will act as a coordinator between the two parties. This effort is expected to benefit Malaysian researchers in terms of the transfer of knowledge, and a spill over of pre-clinical studies to first-in-man/phase 1 studies to complete the clinical research ecosystem in Malaysia.

Memorandum of Understanding between IMR and Aurigene

2016 HIGHLIGHTS

Phase I Realization Project

The Ministry of Health through CRM is driving an initiative to prepare Malaysia to conduct Phase I clinical trials in the next 3 years. This initiative, termed the Phase I Realization Project (P1RP) was design as the Malaysian government wishes to push its involvement in all phases of drug development. Among them are the transfer of knowledge and technologies to Malaysians, as many of these trials test cutting-edge treatments and technologies. Besides, local pharmaceutical and biopharmaceutical industries will also gain first-hand experience in ensuring the efficacy and safety of new drugs.

The 5 pillars that support the P1RP blueprint include the development of Phase I Guidelines, People Development, Capability Development, Preparation of Sites and Risk Management. The initiative that started in May 2016 will see the completion of the Phase I clinical research ecosystem in 2019. The capture of Phase I trials may result in a spill over effect of more Phase II and III trials into Malaysia.

The first Phase I Clinical Trial Guideline Workshop was officiated by the Minister of Health, Datuk Seri Dr S. Subramaniam. The guideline has been developed successfully and will be launched in 2017. The rest of the pillars are currently taking place and it is expected to completed 2019.

Steering Committee Members of the Malaysian Phase 1 Clinical Trial Guideline

CRM TEAM

CONTACT

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