



20



21
ANNUAL REPORT



ABOUT OUR REPORT



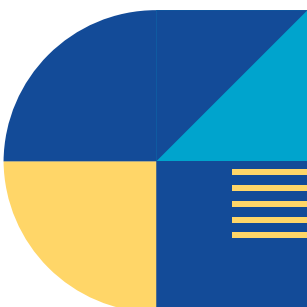
Clinical Research Malaysia (CRM) is proud to share our achievements and success stories in this 2021 Annual Report. We encourage our stakeholders, industry partners, investigators and members of the community to take a moment to read our 6th annual report, which contains information about the important work that our organization does to build a comprehensive research ecosystem in Malaysia.

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.

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



INSIDE THIS REPORT



About Our Report	2
Foreword	4
Board of Directors	5
Organisation Chart	6
About CRM	7
Our Vision & Mission	7
CRM's Core Services	7
Our Core Values	7
Performance Overview	8
Malaysia's Clinical Research Scorecard	8
CRM's Financial Performance	8
Sponsored Research in Malaysia	9
Classification of Clinical Trials	10
Top Sites according to Therapeutic Areas in 2021	13
Site Recruitment Achievement in 2021	14
Feasibility Study Report	14
Sponsors & CROs	16
Online Presence (Website/ Social Media)	16
Placement & Growth of Study Coordinators	17
Recruitment & Study Coordinator Performance	17
Phase 1 Realisation Project	18
CRM Activities 2021	19
Clinical Trials Day & CRM Sponsored Research Awards	22
Publications	23
CRM New Services	24
CRM in Photos	25
What's Next in 2022	27

FOREWORD



4

CLINICAL RESEARCH MALAYSIA

With the continued unprecedented situation of the global Covid-19 pandemic, CRM's income has exceeded its expenses by RM1.8 million. The country's Gross National Income generated by the clinical research industry in 2021 was also above and beyond expectations, with RM226 million, the highest since CRM's establishment in 2012. This speaks of the confidence sponsors and contract research organizations have in Malaysia's potential as a clinical research hub that produces data quality according to the international standards as well as in accordance with the Good Clinical Practice.

In efforts of making CRM a global trusted organization with integrity and ethical conduct, this year, CRM embarked on a journey in obtaining the ISO 37001:2016 Anti Bribery Management System (ABMS) certification, in addition to the recertification of ISO 9001:2015 Quality Management System (QMS). The main objective of obtaining this certification is to manage the risk of bribery and corruption associated with CRM's core processes and business associates and to serve as a basis for decision-making before entering into any contractual arrangement or business dealings. Following the company-wide preparation and implementation, we are proud to announce that CRM's application for ABMS ISO 37001:2016 certification was approved by the Certification Panel of SIRIM QAS International Sdn. Bhd. on 30th of November 2021. In addition, CRM has also successfully received recommendation for recertification of QMS ISO 9001:2015.

For the first time, a third-party vendor was used to obtain CRM customer satisfaction survey from our stakeholders. The overall rate of CRM's core services is up to 89.3% of good and above ratings. CRM will continue to strive in ensuring that we continuously improve on our service delivery as the company grows from strength to strength.

In 2021, CRM has also successfully completed its P1RP initiatives, which was initiated in 2016, to further enhance Malaysia's capability in the development of medical science and therapeutics, especially in early phase studies. With the completion of this project, CRM has further supported the enhancement of FIH capabilities and capacities in Malaysia, by delivering on the needed framework, supporting trainings for regulators, equipping study site with the necessary infrastructure and ensuring an experienced study team is in place.

Finally, I would like to thank everyone in Clinical Research Malaysia for their commitment and perseverance in the face of these uncertain times. As we move into 2022, CRM will continue to strive towards operational excellence, growing ISR, embarking on new opportunities such as home study visits, study material destruction and patient recruitment advertisements, and remaining steadfast to our commitment of speed, quality and reliability in clinical trial deliverance.

Dr. Akhmal Yusof
CEO, Clinical Research Malaysia



BOARD OF DIRECTORS



YB Khairy Jamaluddin

Minister of Health, Malaysia



YBhg. Dato' Mohd Shafiq bin Abdullah

Former Secretary General of Health, Ministry of Health, Malaysia



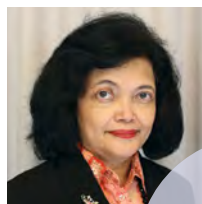
YBhg. Tan Sri Dato' Seri Dr. Noor Hisham

Director General of Health, Ministry of Health, Malaysia



YBhg. Datuk Dr. Hishamshah bin Mohd Ibrahim

Deputy Director-General of Health (Research & Technical Support), Ministry of Health, Malaysia



YBhg. Datuk Dr. Shahnaz Murad

Former Deputy Director General (Research & Technical Support), Ministry of Health, Malaysia



YBhg. Prof. Datuk Dr. A. Rahman A. Jamal

Director, UKM Medical Molecular Biology Institute (UMBI), University Kebangsaan Malaysia (UKM)



Prof. Dr. Abdul Rashid Abdul Rahman

Medical Director and Senior Consultant Physician, An Nur Specialist Hospital



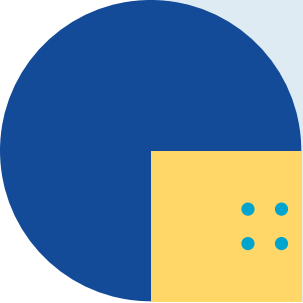
Y. Bhg. Dato' Haji Zein Isma Bin Haji Ismail

Professional Actuary



Mr Ewe Kheng Huat

Former Executive Director of the Pharmaceutical Association of Malaysia (PhAMA)

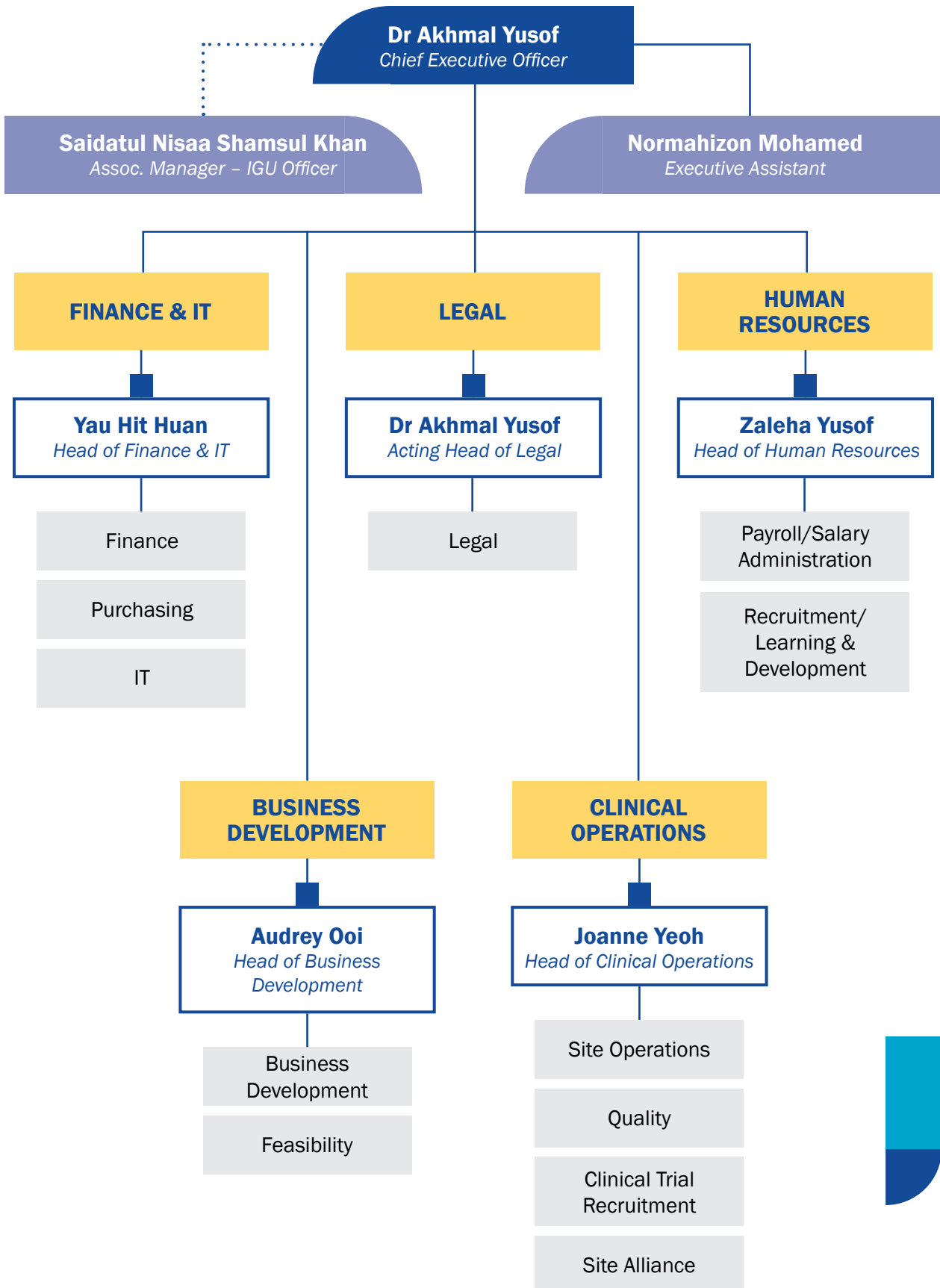


ORGANISATION CHART

6



CLINICAL RESEARCH MALAYSIA





ABOUT CRM

VISION

To make Malaysia the preferred destination for clinical research

MISSION

- Create sustainable value proposition and conduct more clinical research to benefit the country
- Global trusted organisation
- Self-sufficient

CRM'S CORE SERVICES



Complimentary Feasibility Services

Development & Placement of Study Coordinators



Review of Clinical trial Agreement (CTAs) & Non-Disclosure Agreements (NDAs)

Clinical Trial Budget Consultation & Management



Clinical Trial Advertisement

Study Drug Destruction Services



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.



PERFORMANCE OVERVIEW

Malaysia's Clinical Research Scorecard

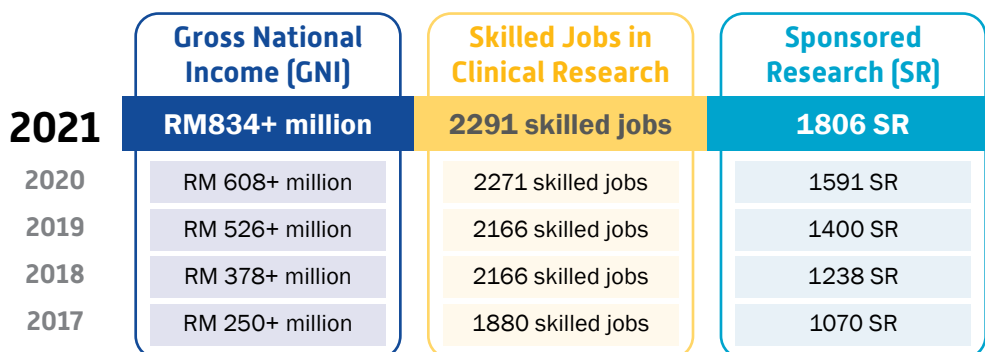


Figure 1: KPI Scorecard from 2017 – 2021

Clinical Research Malaysia was formed in 2012 with the aim to drive more sponsored research into Malaysia. In 2021, a total of RM 226mil investment from Clinical Trial Agreements was reported through the various clinical studies that was conducted by sponsors and CROs in Malaysia, and this brings to the overall cumulative value of over RM834mil in Gross National Income (GNI) (Figure 1). The GNI value in 2021 was the highest value reported since 2012, despite the Covid-19 pandemic experienced by the country in that year.

CRM's Financial Performance

Since 2019, CRM has taken additional measures towards self-sustenance of the company, with no further grants/ subsidies received by the Government of Malaysia. Hence, the company have been implementing measures to narrow the gap between its income and expenditure. In 2020, CRM's income exceeded its expenses. This was maintained in 2021, with its income exceeding its expenses by a total of RM 1.8 million (Figure 2). The company's accumulated gross revenue to equity ratio for the year 2021 is 3.76, marked by a higher revenue generation compared to the overall investment by the Ministry of Health (from 2012 to 2018), and further inferring that the company's business is efficient and self-sufficient in generating its own financial needs (Figure 3).

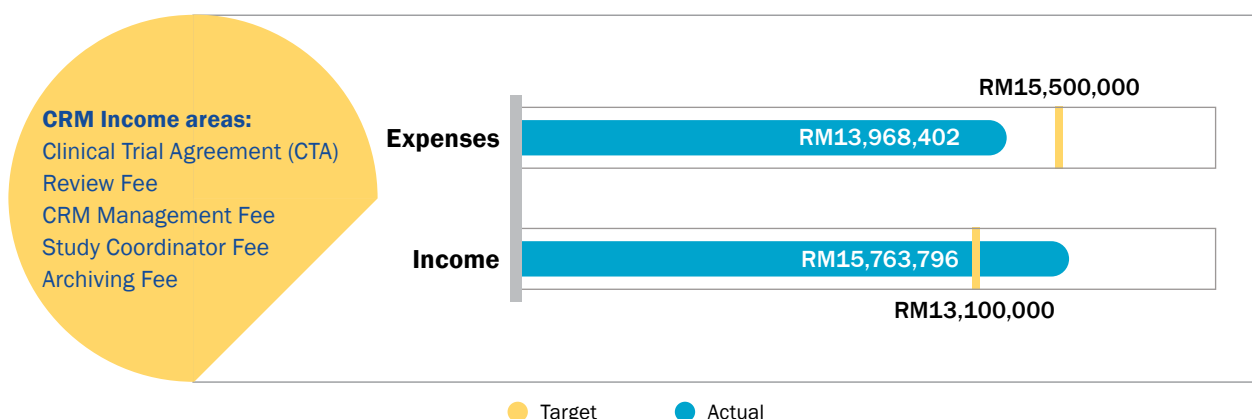


Figure 2: Clinical Research Malaysia Finance Performance in 2021

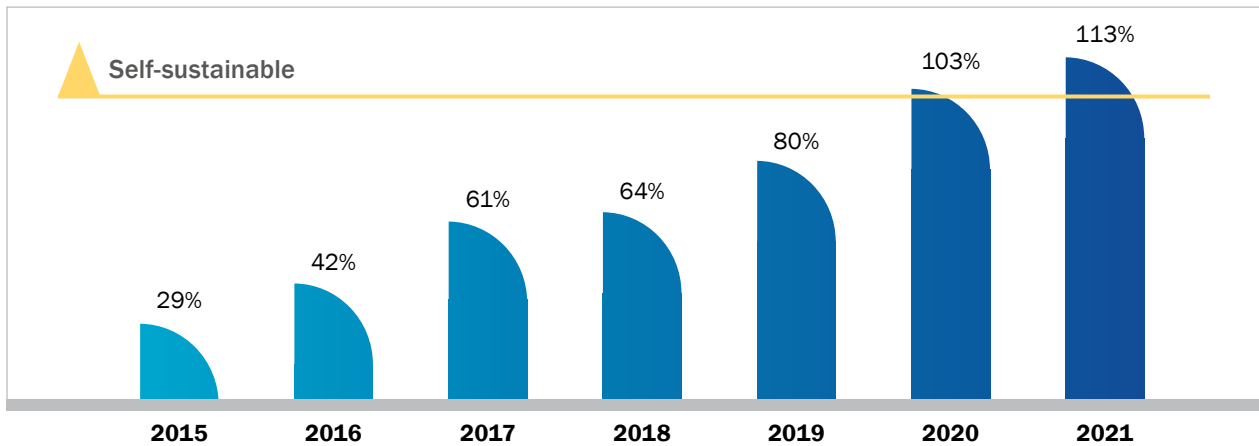


Figure 3: CRM's self-sustainability performance from 2015-2021 (Income / Expenses)

Sponsored Research in Malaysia

A total of 215 sponsored research was approved by Medical Research and Ethics Committee (MREC) and Institutional Review Boards/Independent Ethics Committees (IRB/IECs) in 2021 (Figure 4). This was one of the highest numbers reported in the span of eight years, and translates sponsor/ CRO's confidence in viewing Malaysia as a reliable site for clinical research and strengthening Malaysia's position in sponsored research within the region.

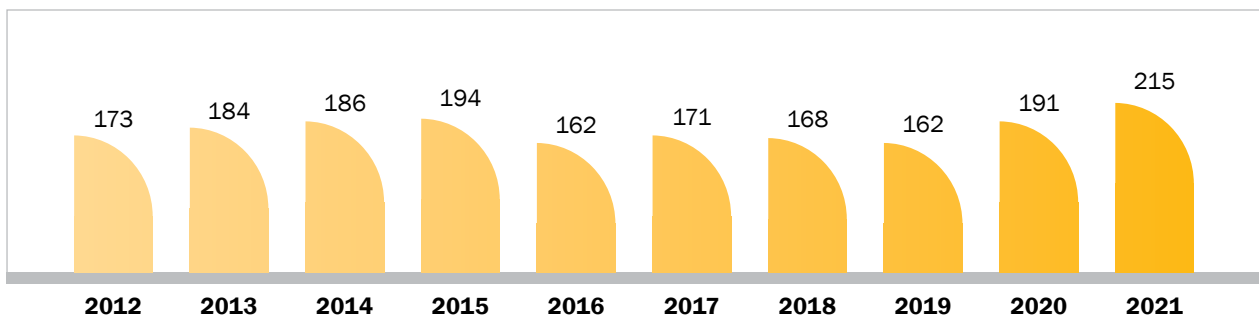


Figure 4: Number of Sponsored Research from 2012 - 2021

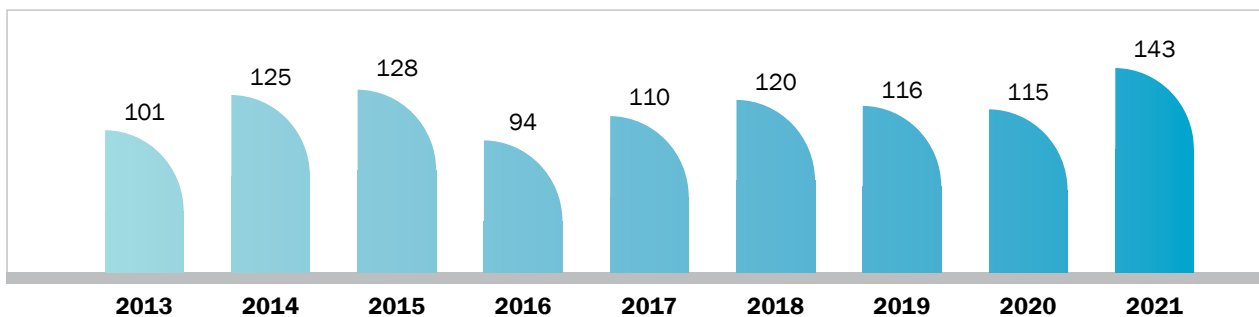


Figure 5: Number of Sponsored Research in MOH sites from 2013 - 2021

Data sourced from MREC shows the trend has also been constant in Ministry of Health (MOH) facilities (Figure 5). More importantly, when both data are observed together, it is noted that at least 45% of sponsored research that were approved are conducted in MOH facilities, showing the recognition these sites have gained owing to its performance in terms of quality and recruitment (Figure 6). This also means majority of patients who seek treatment in public hospitals could access to new innovative drugs through clinical research. At the same time, sponsored research continues to grow at the Ministry of Higher Education (MoHE) sites, involving university hospitals such as University Malaya Medical Center and Hospital Cencelor Tuanku Muhriz.

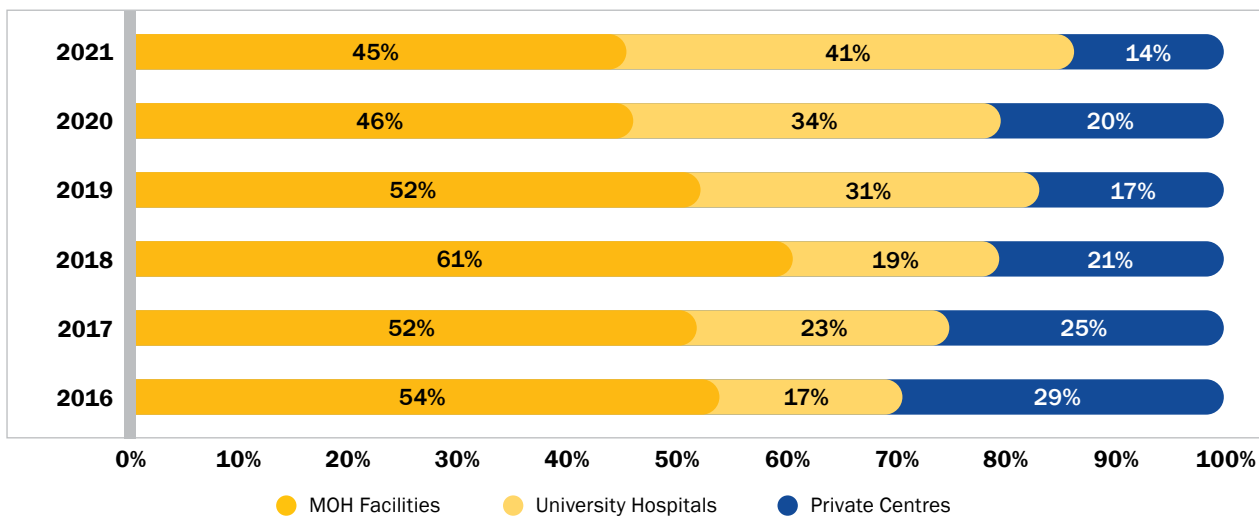


Figure 6: Distribution of Sponsored Research between different site sectors (2016 – 2021)

Note: For multi-centre studies, the same trial could involve multiple sites from different sectors. However, only a single value will be captured under the site sector, irrespective on the number of site(s) within the sector.

Classification of Clinical Trials

More than half of the clinical research conducted in Malaysia in 2021 are interventional, out of which 91 are trials involving drug/ biologics/ vaccine products, 10 bioequivalence studies, 7 medical device trials, 5 on supplements/ herbal products, and the others ranging from procedure, gene therapy and other interventions (Figure 7). Out of all interventional trials, Phase III accounts for majority of trials followed by Phase II, bioavailability/bioequivalence (BA/BE) studies, Phase IV and Phase I (Figure 8). In addition, a declining trend of BA/BE studies are observed over the past five years, with lower numbers recorded yearly, when compared to other interventional studies (Figure 9).

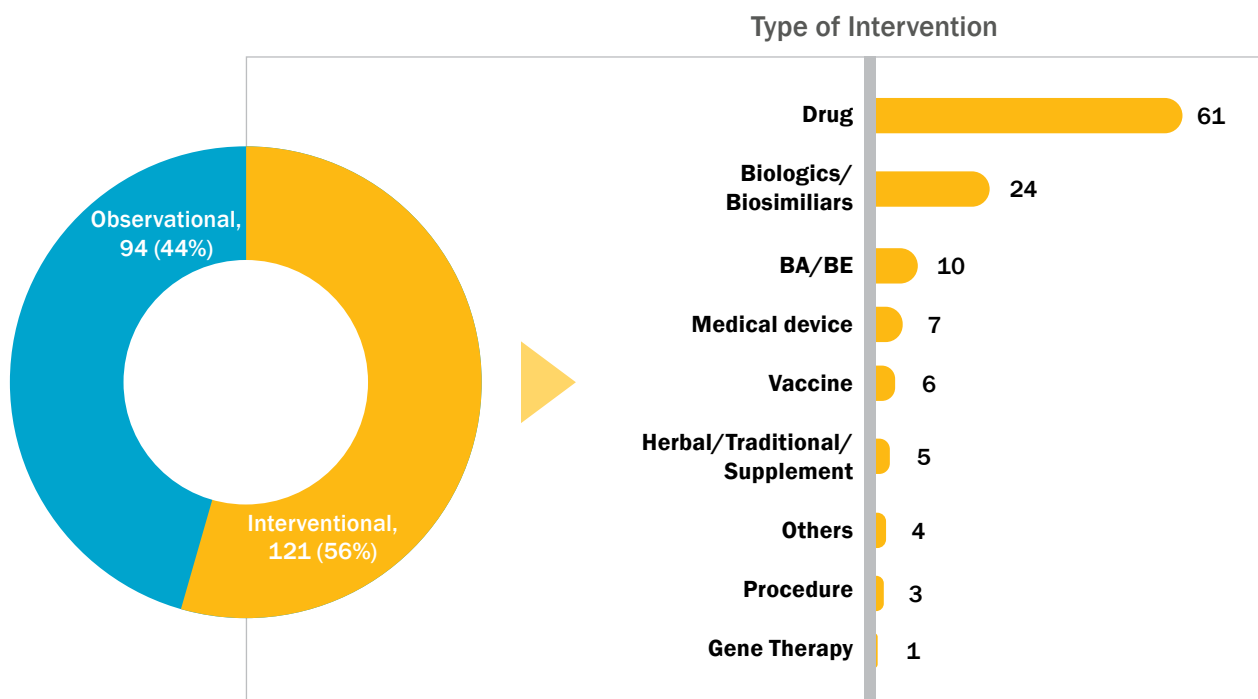


Figure 7: Breakdown of studies according to intervention, 2021

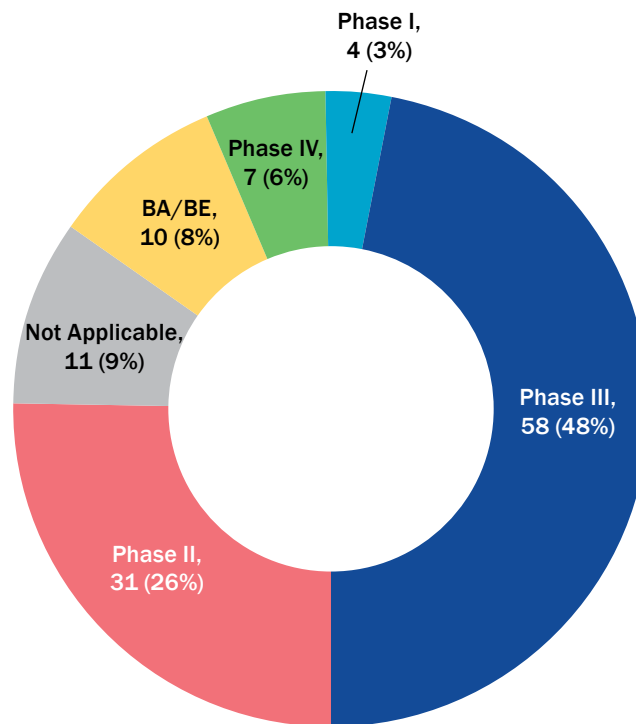


Figure 8: Classification of interventional studies in Malaysia, 2021

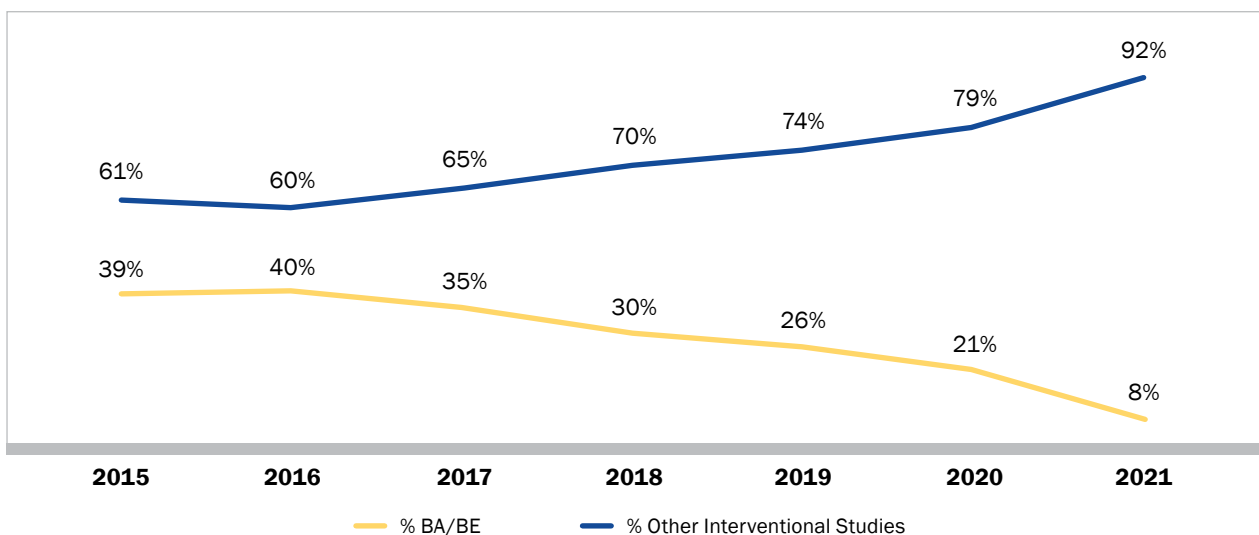


Figure 9: Trend of BA/BE Studies versus Other Interventional Studies, 2015 – 2021

Similar to those in developed countries, Malaysian patients have unmet medical needs and cancer and cardiovascular disease continue to be the major cause of mortality and morbidity in Malaysia. Due to the high prevalence of noncommunicable diseases in Malaysia, it provides a large patient pool for clinical trials in these therapeutic areas. In 2021, due to the need for public health to curb Covid-19 transmission, a high number of research was carried out in this area, especially observational studies in further understanding the disease burden. Hence, despite high number of oncology trials recorded in 2021, infections/ infectious disease research topped the 2021 leader board in research therapeutic areas noted in Malaysia (Figure 10). A deep-dive analysis on the trend of these therapeutic area also depicts an increasing trend in number of studies received, especially in the oncology and infectious disease studies (Table 1).

PERFORMANCE OVERVIEW

12

CLINICAL RESEARCH MALAYSIA



Figure 10: Number of Sponsored Research conducted according to therapeutic area in Malaysia, 2021

Table 1: Trend of Top Therapeutic Studies, 2012 – 2021

THERAPEUTIC AREAS	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Oncology	23	15	18	24	15	18	18	25	32	33
Infections and Infectious Diseases	8	12	7	12	10	6	15	11	24	40
Cardiology/Vascular Diseases	10	22	20	21	18	28	20	14	13	11
Hematology	6	7	12	9	8	5	13	15	11	15
Pediatrics/Neonatology	8	9	4	8	6	7	8	13	6	13

Meanwhile, University Malaya Medical Centre was recorded to have the highest number of trials in Malaysia for 2021 followed by Pulau Pinang Hospital, Kuala Lumpur Hospital, Sarawak General Hospital and Ampang Hospital (Figure 11).

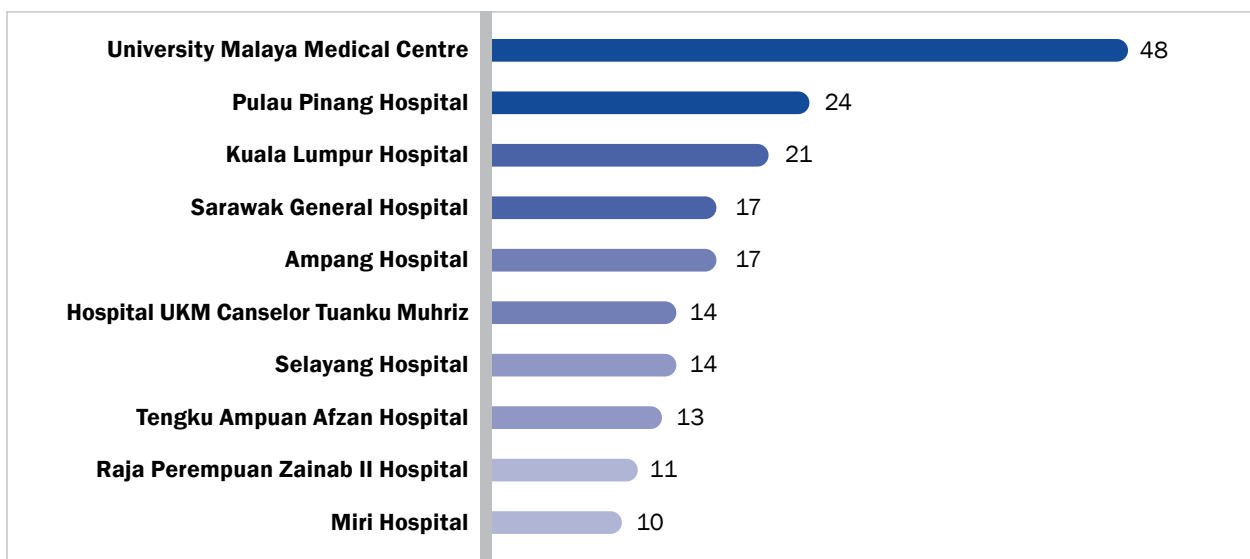


Figure 11: Top sites awarded with sponsored research (interventional studies only) in Malaysia, 2021

Top Sites according to Therapeutic Areas in 2021

CRM has been involved in the trials at most of the Ministry of Health sites, whereby it has assisted investigators in the management of the study budget, feasibility assessments, clinical trial agreement, as well as in providing study coordinators. Below are the top clinical trial sites in 2021 in the field of infections/ infectious diseases, oncology, hematology, cardiology/ vascular diseases and paediatrics/ neonatology (Figure 12).

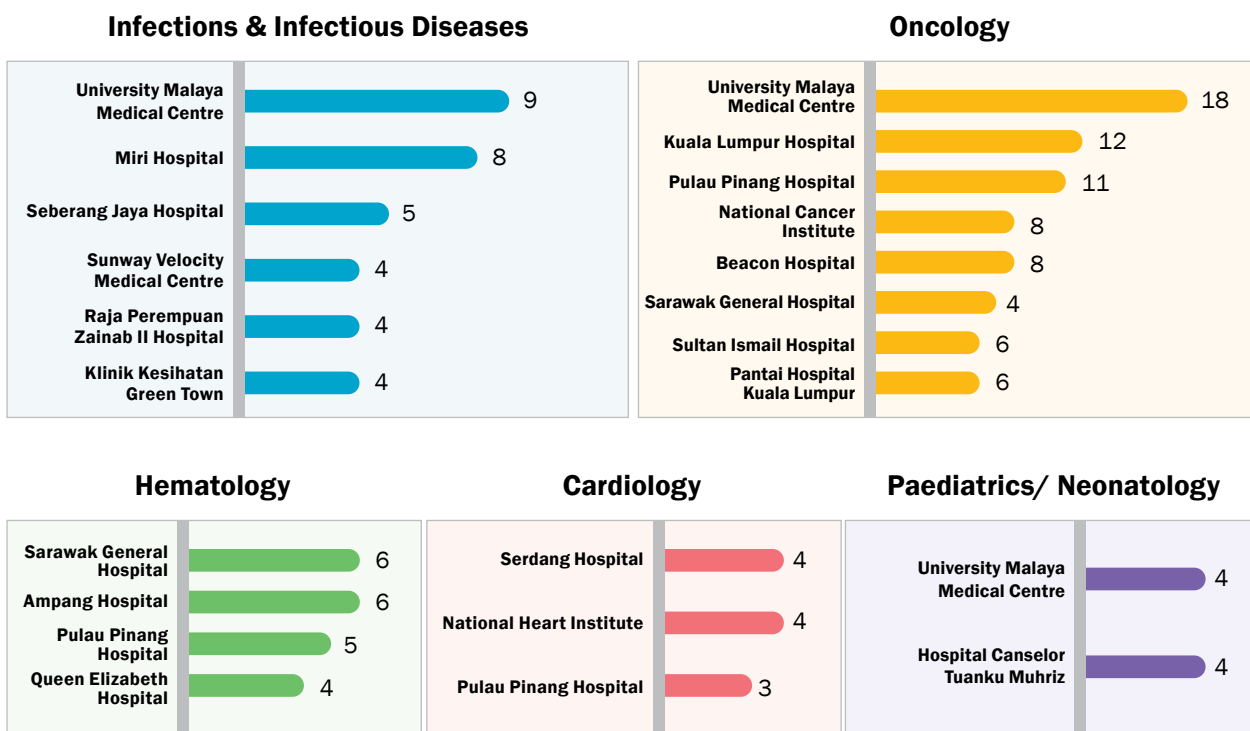


Figure 12: Top sites awarded according to therapeutic area, 2021

Site Recruitment Achievement in 2021

14

To date, there have been 220 study sites in Malaysia that have conducted sponsored research, with 66% of them consisting of public hospitals and government clinics within the Ministry of Health. Many of these sites have performed and delivered the research to the quality and standards as per the Good Clinical Practice (GCP). In 2021, some of the sites/ investigators have earned special recognition from sponsors for their recruitment achievement in global sponsored trials due to their outstanding performance in achieving recruitment target and time set, which further elevates the positive statement on Malaysia's performance and reliability (Figure 13).

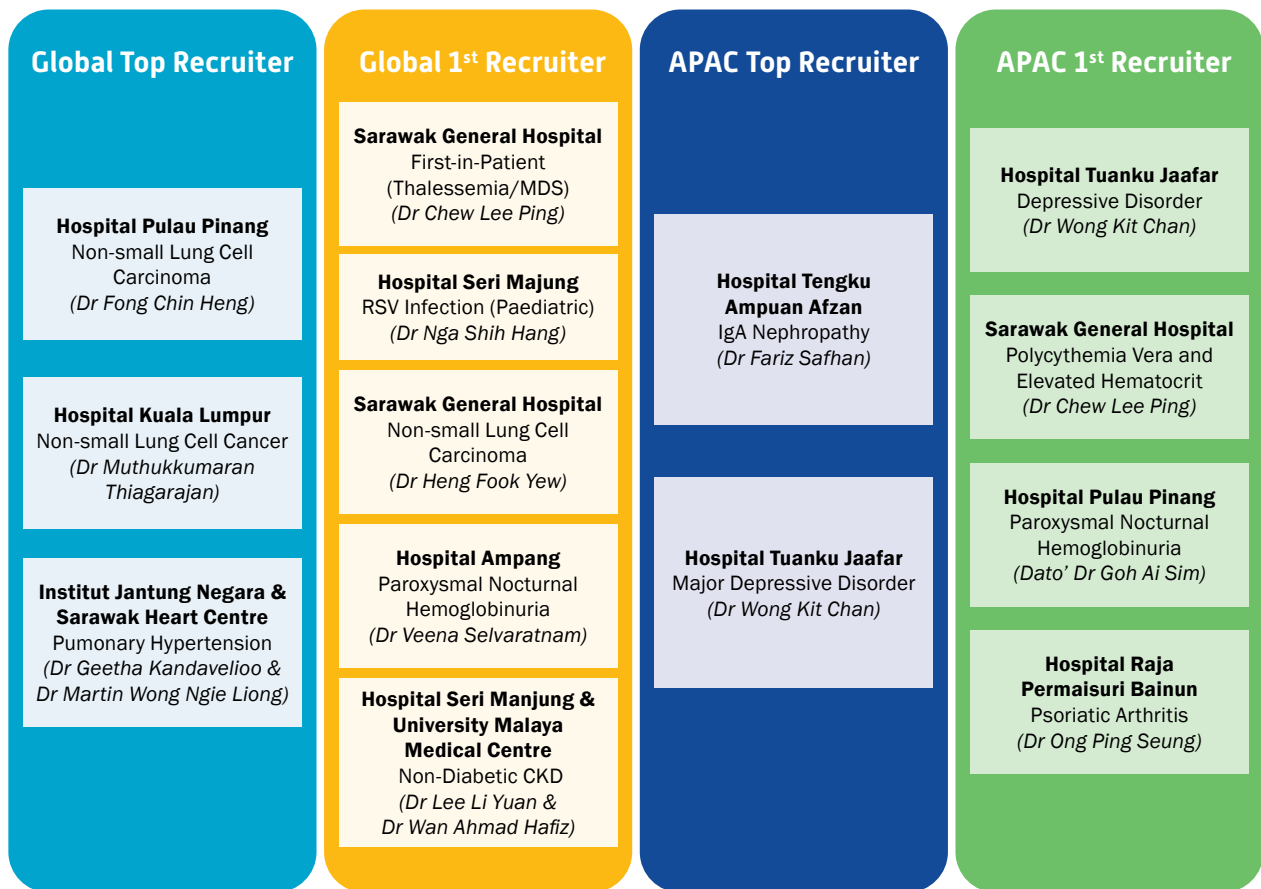


Figure 13: Site recruitment achievement in global trials, 2021

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 a complimentary service provided to sponsors and CROs who may be interested in conducting clinical trials in Malaysia. In addition to full-feasibility, CRM also assisted with pre-feasibility enquiries which are otherwise known as country level feasibility. In 2021, the number of full-feasibility overtook pre-feasibility queries for the first time since the establishment of this service, pointing to a deeper level of data need by sponsors and CROs to gain insight on the suitability of Malaysian site(s) in the study proposed (Figure 14). Most feasibility studies received were studies in infections/ infectious diseases followed by oncology, haematology and nephrology (Figure 15).

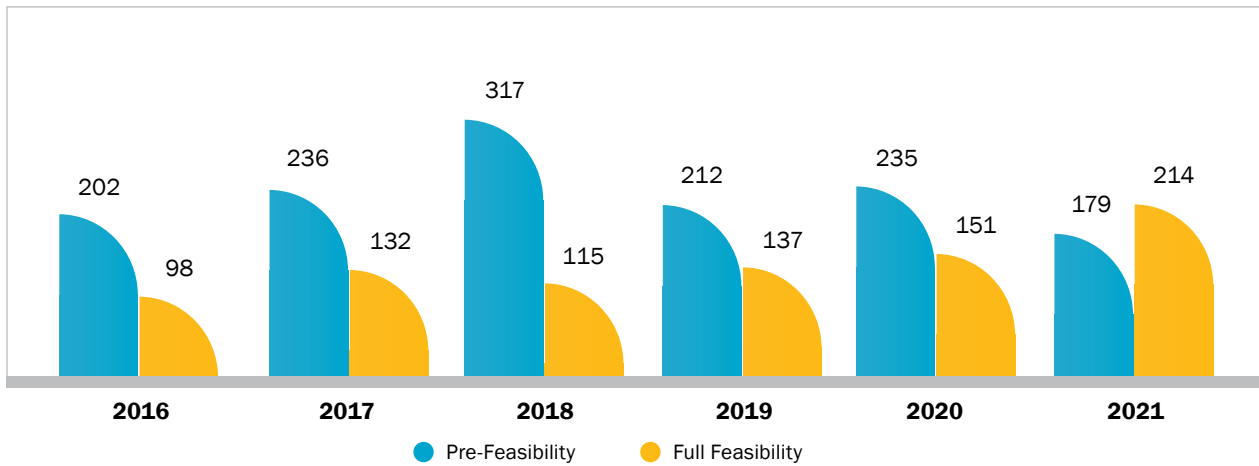


Figure 14: Pre-Feasibility & Full Feasibility from 2016 – 2021

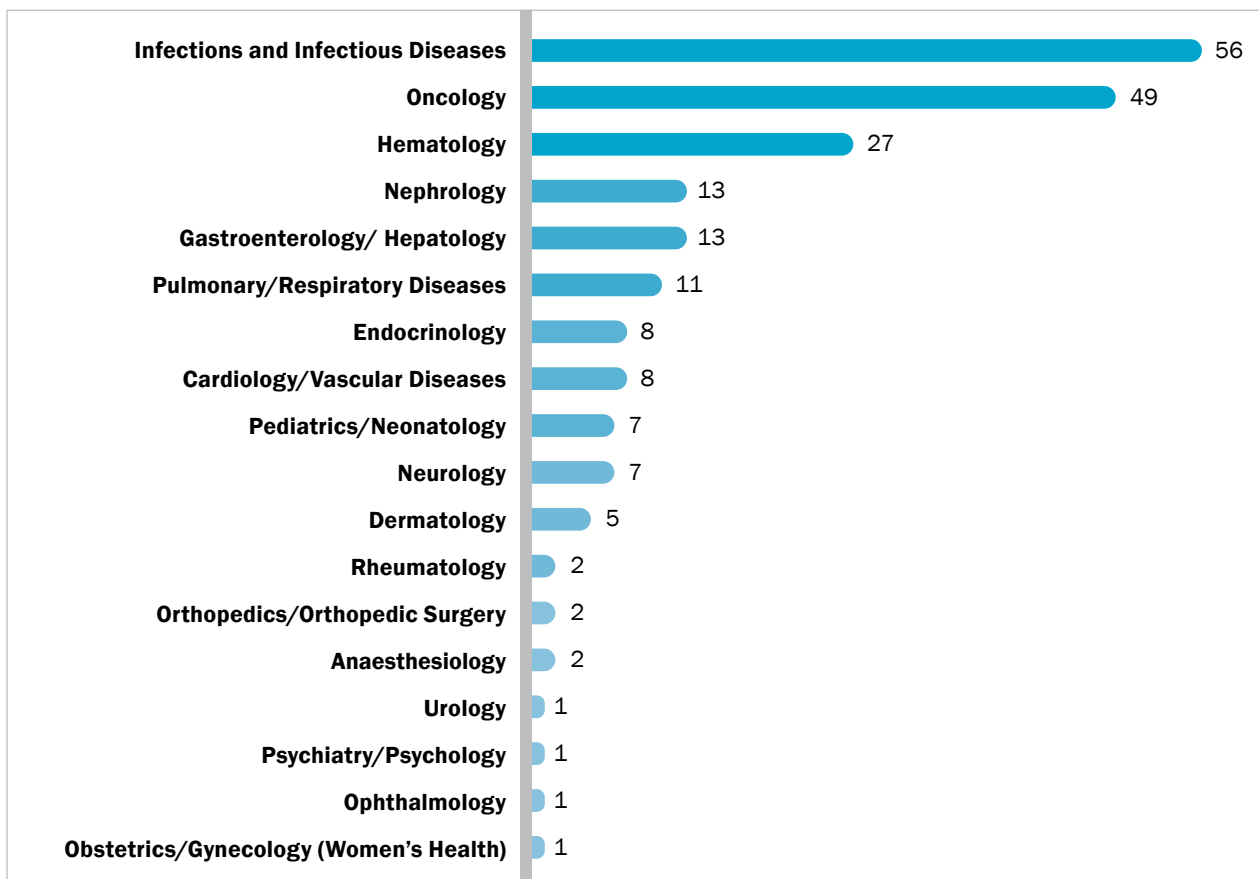


Figure 15: Full Feasibilities received in 2021 by Therapeutic Area

Sponsors & CROs

16

CRM has been promoting Malaysia's capabilities and capacities in clinical research since its establishment in June 2012 as it is essential for Malaysia to be viewed as a preferred destination for multinational sponsored research. The growth of sponsors and CROs that have engaged with CRM has been evident in showing the growing effect Malaysia has in the global clinical trial landscape (Figure 16). Many of these global Sponsors & CROs also contribute to the number of sponsored research awarded (Figure 17).

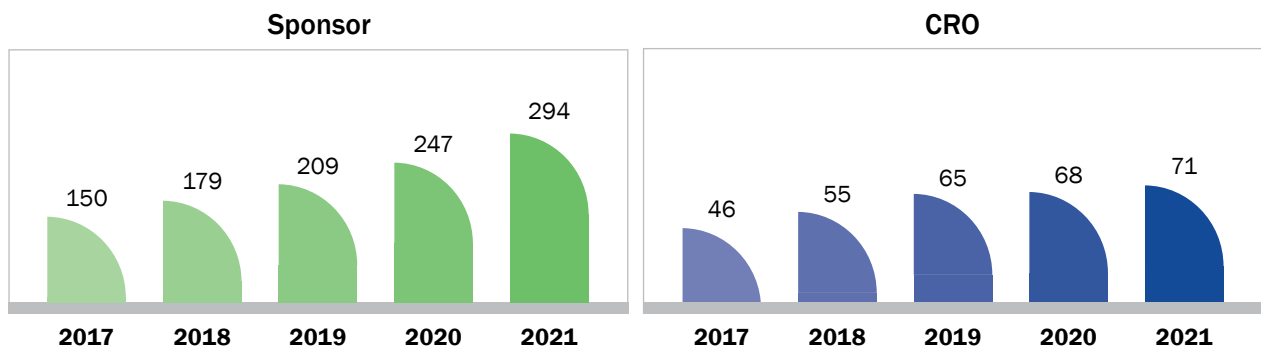


Figure 16: Sponsors & CRO that have engaged with CRM

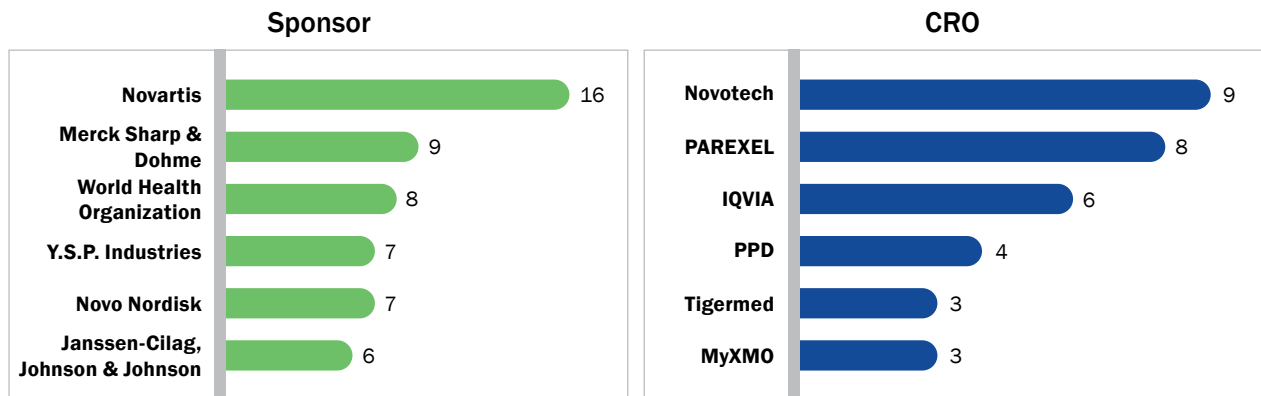


Figure 17: Top contributors in number of new sponsored research by Sponsors & CROs for 2021

Online Presence (Website/ Social Media)

CRM has also capitalised on its website and social media reach, with 38% increase noted in the number of visits and impressions for year 2021 compared to 2020 (Figure 18). The online followers and support gained over the years are essential in further driving CRM's clinical trial advertisement service, which provides sponsors and CROs the needed platform to increase awareness of a clinical trial to the public.

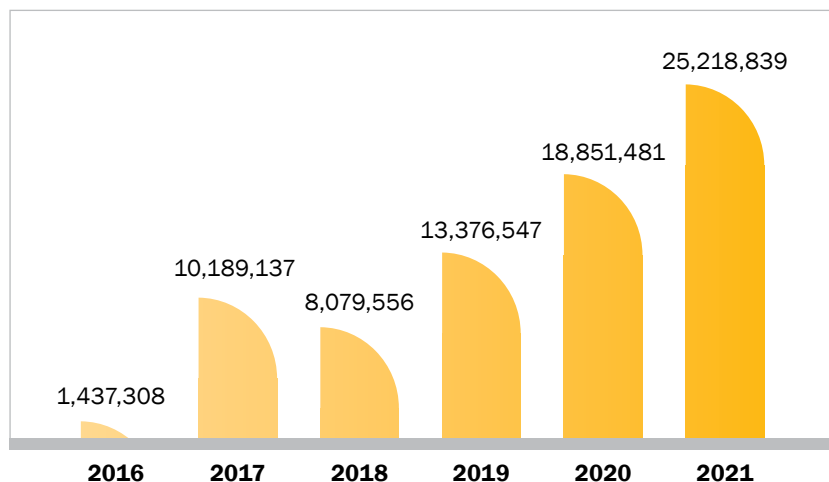


Figure 18: CRM website/ social media visits & impressions from 2016 – 2021

Placement & Growth of Study Coordinators

At the establishment of CRM in 2012, it had 22 study coordinators that were placed throughout Malaysia at various sites conducting sponsored research and this number have grown to 150 in 2021 (Figure 19 & 20). CRM has expanded its provision and placement of study coordinators beyond the realm of public hospital, to include primary health care centres & private hospitals.



Figure 19: CRM Placement of Study Coordinators in 2021

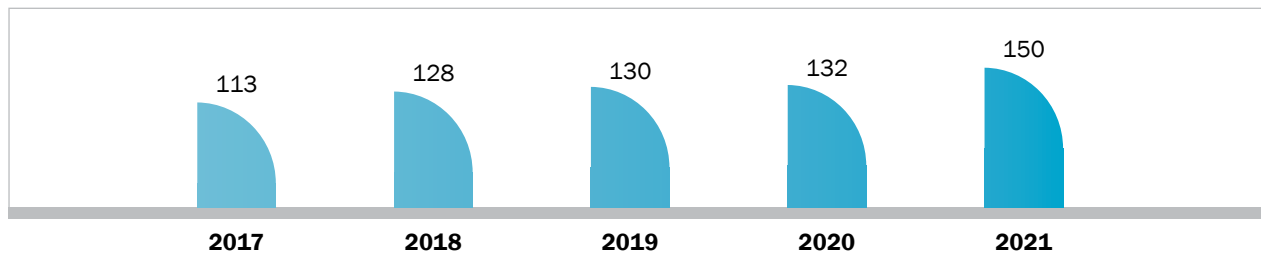


Figure 20: Growth of number of CRM Study Coordinators from 2017 – 2021

Recruitment & Study Coordinator Performance

To deliver a study conduct with speed, quality and reliability, CRM's Clinical Operations team factor in CRM's study coordinators' performance via feedback from stakeholders which are tabulated as a measurement on the overall accomplishment of study coordinators. This year's CRM's customer satisfaction survey was conducted by a third-party vendor to ensure neutrality of the survey outcome. About 89% of stakeholders rated good and above for CRM study coordinator services. Additionally, the average percentage of recruitment achieved in 2021 in studies involving CRM study coordinators was at 86%. The recruitment in a study is routinely monitored and the challenges are explored together with discussion between study team and sponsor. These led to a positive data in terms of recruitment and overall study coordinators performance in 2021 (Figure 21).

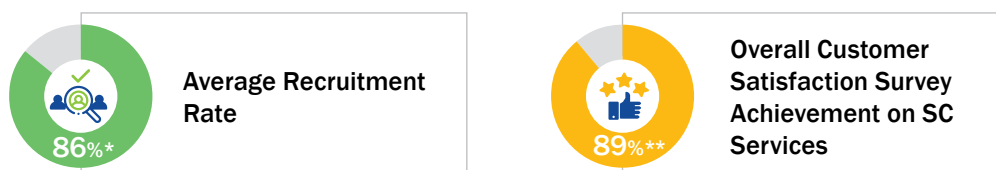


Figure 21: Clinical Operations Performance in 2021

* Average percentage of recruitment achieved in 2021 in studies involving CRM study coordinators

** Data from CRM Customer Satisfaction Survey 2021, conducted by Vase.ai



PHASE 1 REALISATION PROJECT

18

CLINICAL RESEARCH MALAYSIA

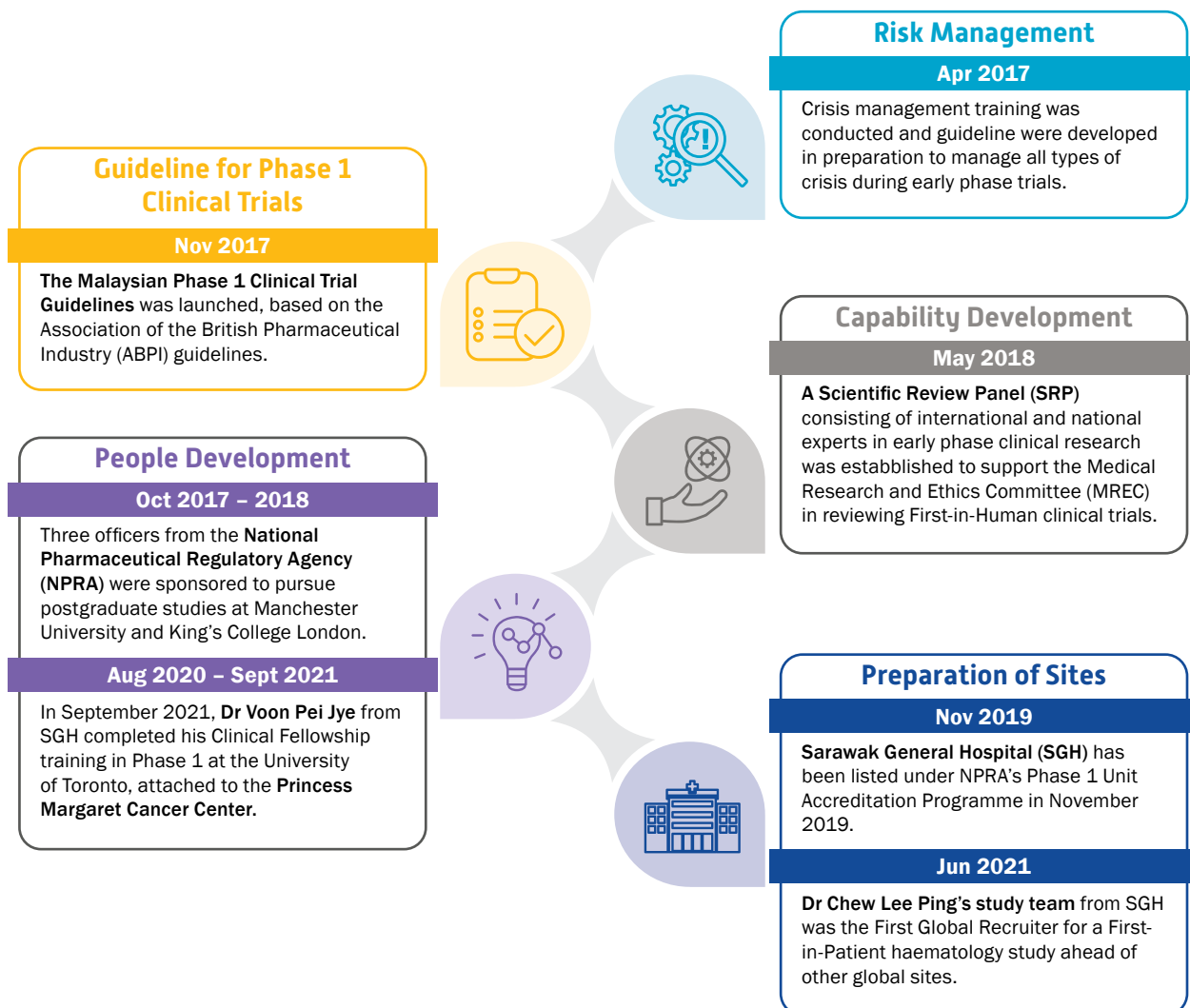
Early phase studies are vital to further enhance Malaysia's capability in multi-therapeutics drug development. The Phase 1 Realisation Project (P1RP) initiative which was initiated by CRM in 2016 was developed primarily for the purpose to enable and drive early phase research in Malaysia through its five identified pillars.

In 2021, the P1RP project marked its completion in 2021, wrapping 18% savings from its budget of RM2,600,000. Under the P1RP, the development of the Guidelines for Phase 1 Clinical Trial was the precursor to the rest of the initiatives that took place, including the Phase 1 Unit Inspection and Accreditation Program by NPRA. With the completion of this project, CRM has further supported the enhancement of First-in-Human (FIH) capabilities and capacities in Malaysia, by providing exposure and training in early phase drug development to Malaysia's regulators and investigator, equipping trial sites with the necessary infrastructure for early phase study and the establishment of a Scientific Review Panel (SRP) to support the Medical Research and Ethics Committee (MREC) in reviewing First-in-Human studies.

In March 2021, the first FIH study was approved to be conducted in Sarawak General Hospital. Prior to its ethics approval, the study underwent scientific review by the SRP and was also reviewed by the FIH Panel of Experts (POE) during the regulatory review. Following the study conduct at site, the study investigator, Dr Chew Lee Ping subsequently became first global recruiter ahead of other global sites for this study, marking significant study achievement and progress for Sarawak General Hospital.

PHASE 1 REALISATION PROJECT (P1RP)

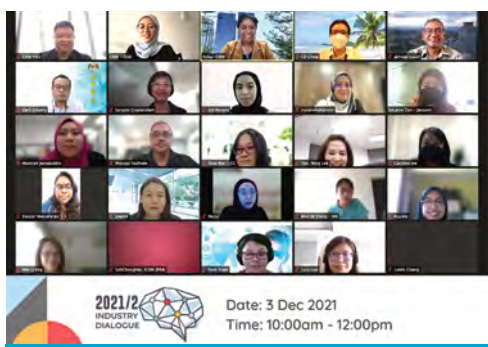
The Result





CRM ACTIVITIES 2021

CRM has participated and conducted numerous activities and events throughout year 2021, some with close collaborations with both local and global stakeholders. Among notable participations were CRM's presence in programs organised by both the Japanese Society of Medical Oncology (JSMO) and Japan Pharmaceutical Society, in which CRM presented on Malaysia's clinical research ecosystem and growing opportunities for drug development. On the local front, CRM was the co-organiser in the annual National Conference for Clinical Research (NCCR) together with Institute for Clinical Research (ICR). CRM also formed new partnerships and business collaborations through the inking of Memorandum of Understandings with both Docquity and University of Technology MARA (UiTM), in efforts to further elevate awareness and interest on clinical research in Malaysia and in developing an accredited Bioequivalence centre in UiTM Hospital respectively. In addition, CRM has also conducted numerous trainings, workshops, and dialogues throughout the year to ensure continuous engagement with stakeholders.



Industry Dialogue 2021

CRM had two virtual Industry Dialogues in 2021, which were conducted in the presence of industry representatives with regulatory/ ethics involvement. The first Industry Dialogue was carried out as a 2-day program in April 2021 featuring webinar and panel discussion, with the focus being on Decentralised Clinical Trials (DCT) in Malaysia. The second dialogue was held in December 2021, and was focused on pertinent updates by NPRA and MREC, especially on the recent regulatory developments pertaining to First-in-Human studies in Malaysia.

Good Clinical Practice (GCP) Refresher Workshop

GCP refresher workshops are organized by CRM to serve as a platform for investigators and research team to enhance the competence in managing a clinical trial conduct. In 2021, the workshops were conducted in a series, namely on Informed Consent Process, IP Management in Clinical Trial, Safety Reporting (AE/SAE Management) & Good Documentation & Site File Management.



I AM AWARE

CRM's I AM AWARE continued in 2021 with the aim to enhance awareness about clinical research among the public. Just as the year before, the campaign was driven through CRM's social media platforms, with the focus on educating others about clinical research.

TIPS Training

Training to Improve Performance of Study coordinators (TIPS) is conducted to share best practices amongst study coordinator to sharpen their study conduct skills and knowledge. In 2021, CRM conducted nine sessions across regions in Malaysia including Northern, Southern, Central, East Coast and East Malaysia, attended by over 130 study coordinators. CRM also conducted a session for the line managers within Clinical Operations, focused on implementing 'kaizen' to further improve site operations.



Investigator Dialogue

CRM held its virtual Investigator Dialogue 2021, themed 'Decentralised Clinical Trials in Malaysia'. This yearly dialogue was conducted to enable a platform for clinical researchers in Malaysia to discuss and highlight issues and opportunities for research conduct at site. In the dialogue, the panel members, consisting of representatives from ICR, NPRA, MREC as well as industry, shared relevant inputs in bridging virtual trial practices at sites.

Protocol Compliance Workshop

The Protocol Compliance workshop is an interactive workshop involving discussion on the current Protocol Deviation (PD) trend. The workshop is an important training to provide awareness to the investigators and research team through lessons learnt and experience sharing. The speakers of the program present common cases noted as well as suggestions in handling and preventing PD. In 2021, CRM conducted two Protocol Compliance Workshops.



Nurturing New Talent in Sponsored Research

Nurturing New Talents in Sponsored Research is conducted with the aim to develop and grow the pool of investigators in clinical research. In 2021, CRM conducted three virtual seminars, with close to 100 clinicians, pharmacists and nurses gathered during each program.

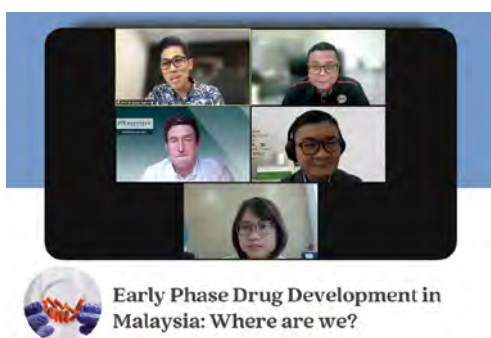
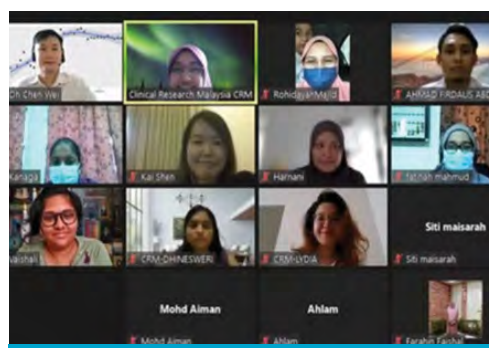


CRM-NPRA Good Submission Practice Training

In efforts of encouraging the conduct of high potential and impactful First-In-Human studies in Malaysia, CRM together with NPRA, conducted the Good Submission Practice Training. Presented by Dr Zaril Harza Zakaria (Head of Evaluation & Safety of Investigational New Product Section), the training was focused on familiarising industry members with processes involved in First-In-Human CTIL submission.

Preparation of Regulatory Inspection Workshop

Conducted by CRM in collaboration with the Good Clinical Practice (GCP) & Good Laboratory Practice (GLP) Section within NPRA, the workshop is aimed for investigators and study teams to learn and share best practices for regulatory site inspections. Two workshops were conducted in 2021.



CRM Webinar: Early Phase Drug Development in Malaysia: Where Are We?

CRM conducted its first webinar which was attended by investigators, CRO representatives, regulatory authorities and ethic committees. The panel members shared their knowledge and experiences in early phase drug development preparation & conduct during this webinar, to provide an overview of early phase drug development in Malaysia.

Patient Recruitment and Retention Workshop

CRM has successfully conducted three Patient Recruitment & Retention Workshops, in March, July and November 2021. The main objective of this workshop was to explore how to maximise recruitment approaches by sharing best practices, and was attended by study team members at sites.



CLINICAL TRIALS DAY & CRM SPONSORED RESEARCH AWARDS

22

CLINICAL RESEARCH MALAYSIA

Clinical Research Malaysia celebrated International Clinical Trials Day in May 2021, aimed in recognising and honouring the contributions of the clinical research community in Malaysia and the world. With the tagline 'Be Informed', the month-long program was conducted virtually, during which CRM shared pertinent information & facts on clinical trial via CRM's social media platforms.

The CRM Sponsored Research Awards were also presented during this month, to six recipients in recognition of their significant contribution in clinical research. Clinicians who received the award include Dr. Soo Hoo Hwoei Fen (Clinical Oncologist) from Hospital Pulau Pinang and Associate Professor Dr. Lim Soo Kun (Nephrologist) from University of Malaya Medical Centre (UMMC) for contributing towards good clinical trial patient recruitment and high number of sponsored research uptake respectively. UMMC and Hospital Kuala Lumpur were both recognized as Clinical Trial Site of the Year for being among the top sites in the nation that conducted high number of sponsored studies in 2020. Janssen (Pharmaceutical companies of Johnson & Johnson), received Sponsor of the Year award for bringing in the highest value of new trials in 2020, while IQVIA Malaysia received CRO of the Year award for contracting the highest number of new clinical trials in 2020.





PUBLICATIONS



20
February

As of 2021, CRM has published **17 articles** in peer-reviewed journals, with 4 just published in 2021!

Impact of COVID-19 on Clinical Research in Malaysia – *Journal for Clinical Studies*

<https://journalforclinicalstudies.com/wp-content/uploads/2021/02/Impact-of-COVID-19-on-Clinical-Research.pdf>



4
March

Legal Perspectives on Conducting Clinical Trials During COVID-19 Outbreak in Malaysia – *Applied Clinical Trials*

www.appliedclinicaltrialsonline.com/view/legal-perspectives-on-conducting-clinical-trials-during-covid-19-outbreak-in-malaysia



31
April

Paving the Way for a Robust Research Ethics Review Structure in Malaysia – *Journal for Clinical Studies*

<https://clinicalresearch.my/wp-content/uploads/2021/05/Paving-the-Way-for-a-Robust-Research-Ethics.pdf>



6
August

A View of Electronic Signature in Clinical Trial Agreements in Malaysia – *Applied Clinical Trials*

<https://www.appliedclinicaltrialsonline.com/view/a-view-of-electronic-signature-in-clinical-trial-agreements-in-malaysia>

CRM NEW SERVICES

24

CLINICAL RESEARCH MALAYSIA



CLINICAL TRIAL ADVERTISEMENT SERVICES



PLATFORM

- Facebook & Instagram
- Targeted audience approach via Sponsored Ads.



STUDY DRUG DESTRUCTION SERVICES



- Provide proper and adequate handling of study drug disposal
- Outsourced vendor with certified ISO 9001:2015, ISO 14001:2015 and ISO 45001:2018
- Service provided complies with strict Standard Operating Procedures & Good Clinical Practice

CRM IN PHOTOS



5 FEB

Meeting with Major Dato Huan Cheng Guan and Encik Abu Baharin



11 MAR

Delegation from Pharmaniaga Berhad led by Datuk Zulkarnain Md Eusope (Group Managing Director) and En Mohamed Iqbal (Group Deputy Managing Director)



19 MAR

CRM's 1st Board of Director's Meeting



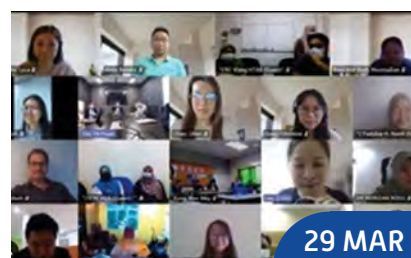
22 MAR

Meeting with Mr Philip Ting & Dato' Seri Dr Chen Chaw



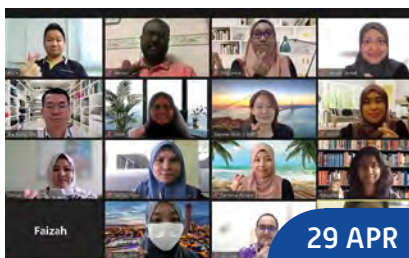
25 MAR

Subject Recruitment & Retention Workshop



29 MAR

1st Prime Site Joint Steering Committee Meeting (JSC)



29 APR

CRM TIPS Training



30 APR

Met with Mr Chong Boon Seng (Everspring Co Ltd)



5 MAY

1st CRM GCP Refresher Workshop



21 MAY

Training to Improve Performance of Study Coordinators



16 JUN

Investigator Dialogue 2021



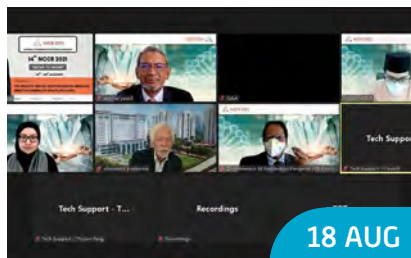
30 JUN

Protocol Compliance Workshop



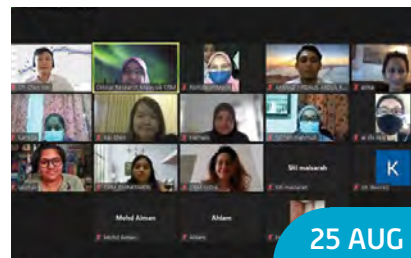
14 JUL

Patient Recruitment & Retention Workshop



18 AUG

The National Conference for Clinical Research 2021



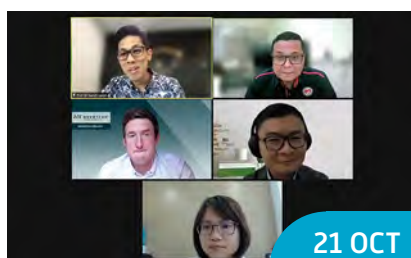
25 AUG

Preparation for Regulatory Inspection Workshop 2021/1



15 SEP

3rd GCP Refresher Workshop



21 OCT

CRM Webinar: Early Phase Drug Development in Malaysia: Where are we?



1 NOV

Launch of National Vaccine Development Plan at Malaysian Genome Vaccine Institute



10 NOV

4th GCP Refresher Workshop



18 NOV

3rd BOD Meeting



24 NOV

Preparation for Regulatory Inspection Workshop 2021/2



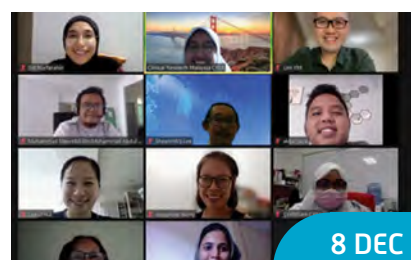
1 DEC

NPRA Good Submission Practice Training



3 DEC

Industry Dialogue 2021/2



8 DEC

2nd Protocol Compliance Workshop

WHAT'S NEXT IN

Operational
Excellence
+
Key Strategies

Global Trusted
Research
Management
Organisation

New
Opportunities

2022

Moving forward in 2022, CRM will continue to work towards Operational Excellence and focus on its four key strategies which are:

- (i) Growing Investigators and Sponsored Research;
- (ii) Collaborating with Stakeholders;
- (iii) Creating Awareness on Clinical Research; and
- (iv) Developing its Human Capital.

CRM will be exploring new business opportunities that facilitate clinical research operations at site, including home study visits and management services for government scientific grant, as well as further expanding the reach of its newly introduced services, Clinical Trial Advertisement Service and Study Material Destruction Service. CRM will also be working towards increasing the number of sponsored research in the country by creating awareness and leveraging on promotion activities via CRM's online presence, attracting more new high value sponsored research, engaging with new institutions and sponsors and continue to strengthen early phase capabilities especially in the conduct of First-in-Human (FIH) studies in the country.

CRM will also be ensuring its continual certification of ISO 9001:2015 Quality Management System and ISO 37001:2016 Anti-Bribery Management System to ensure deliverance of speed, quality, and reliability in the services it provides, continuing its pursuit in becoming a Global Trusted Research Management Organization.

www.clinicalresearch.my

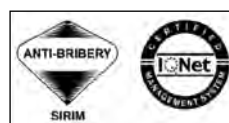


Your Global Solutions in One Nation

D-26-06, Menara Suezcap 1, KL Gateway, No. 2 Jalan Kerinchi,
Gerbang Kerinchi Lestari, 59200 Kuala Lumpur, Malaysia.

T: +603-7931 5566 | **F:** +603-7931 9940 | **E:** contact@clinicalresearch.my

© 2022 Clinical Research Malaysia. All Rights Reserved.



CERTIFIED TO ISO 37001:2016
CERT NO.: ABMS 00218



CERTIFIED TO ISO 9001:2015
CERT NO.: QMS 03360