



20



23
ANNUAL REPORT



ABOUT OUR REPORT

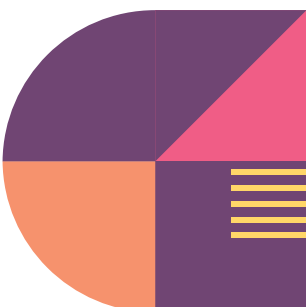


Clinical Research Malaysia (CRM) is proud to share our achievements and success stories in this 2023 Annual Report. We encourage our stakeholders, industry partners, investigators and members of the community to take a moment to read our 8th annual report, which contains information about the important 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 the sponsored clinical research milestones achieved under CRM's guided principles of **HUMANITY, STABILITY & SUSTAINABILITY**. With CRM's focus in bridging unmet needs in patient care through clinical trials (**HUMANITY**) and creating the professional clinical trial management ecosystem that consistently delivers trials with speed, quality & reliability (**STABILITY**), Malaysia is now at a prominent position in the footprint of global trials. Finally, in the trust built with the stakeholders, CRM is committed to create a conducive, sustainable clinical research environment, as a Global Trusted Research Management organisation (**SUSTAINABILITY**).



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FOREWORD



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CLINICAL RESEARCH MALAYSIA

As we reflect on the remarkable strides made by CRM in 2023, it's evident that we stand at the threshold of an exciting decade ahead. Our first strategic meeting not only set the tone but also outlined key missions and strategies for the period spanning 2023 - 2033. Ensuring trials are conducted with speed, quality, and reliability will be crucial in boosting stakeholders' confidence in choosing CRM as their preferred partner, thus attracting more sponsored research to Malaysia.

In 2023, Malaysia ranked second in the number of global industry-sponsored trials conducted in South East Asia region, reflecting our commitment to advancing clinical research. This dedication translated into tangible results, as reflected in our significant contribution of RM1.16 billion to Malaysia's Gross National Income (GNI) accumulated since 2012.

The past year has been a whirlwind of activity for CRM, marked by impactful engagements and discussions with our stakeholders and partners locally and internationally. Notable highlights include our participation in international forums such as ESMO Madrid and the Partners Consultation Program hosted by the Princess Margaret Cancer Centre in Canada. Additionally, our 2nd annual CRM Trial Connect Conference was our biggest highlights with a resounding success. As for early phase studies, CRM continues to enhance Malaysia's early phase capabilities through the Phase 1 Realisation Project (P1RP) 2.0. Through our engagements with world-class early phase centers in Canada, Japan, Australia & Singapore, we are collaborating to train and develop Malaysia's investigators and study coordinators, ensuring readiness of our study team in conducting First-in-Human studies.

I want to express my sincere gratitude to everyone at Clinical Research Malaysia for their unwavering dedication and perseverance. As we venture into 2024, let's remain steadfast in our commitment to Humanity, Stability, and Sustainability. Together, we'll continue to pursue our vision of positioning Malaysia as the preferred clinical research hub in Asia by 2033.

Dr. Akhmal Yusof
*Chief Executive Officer,
Clinical Research Malaysia*

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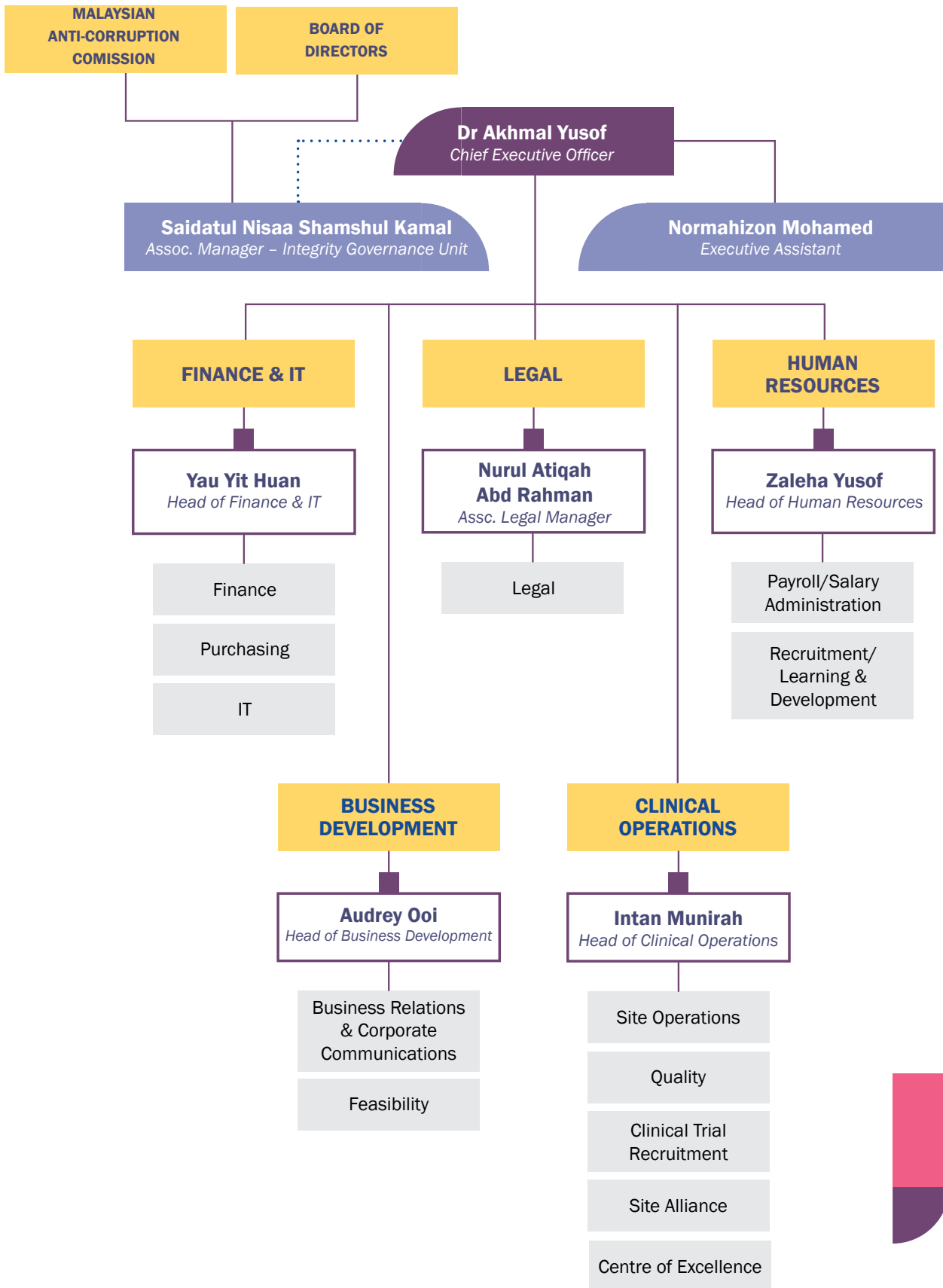
Mr Ewe Kheng Huat

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

ORGANISATION CHART

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CLINICAL RESEARCH MALAYSIA








ABOUT CRM

VISION

To make Malaysia the preferred hub for clinical research in Asia

MISSION

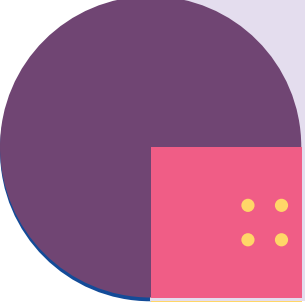
-  Global Trusted Research Management Organisation
-  Clinical Research Professions Development
-  Digitalise Processes

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 Material Destruction Services
-  Archiving of Study Documents

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.



CRM'S GUIDING PRINCIPLES



HUMANITY

Addresses unmet medical needs, access to innovative treatments and transform health outcomes for patients through clinical trials



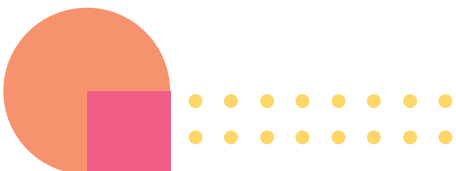
STABILITY

Excellent & consistent performance to deliver with speed, reliability & quality



SUSTAINABILITY

Create business sustainability through core values, code of conduct & operational excellence



Meeting Unmet Needs Through Clinical Research

Clinical trials play a crucial role in identifying effective new diagnostics and treatments to address the high burden of communicable and non-communicable diseases in developing countries such as Malaysia. Improving access to clinical trials and eliminating significant barriers to clinical trial participation are some of the main drivers in bringing clinical trials to Malaysia. Clinical trial participation serves as a gateway for participants to access potential new treatment and high-quality medical care by a highly trained team of health professionals.

Conducting a feasibility study is an essential initial step in the process of clinical trial conduct. During this phase, sponsors assess the possibility of conducting a clinical trial in Malaysia. Successfully completing a feasibility study not only serves as a gateway to attracting more clinical trials to Malaysia but also showcases Malaysia’s capability and capacity in conducting clinical research. This, in turn, enhances the country’s reputation as a destination for clinical trials and promotes collaboration between local and international stakeholders in advancing medical research and healthcare innovation.

Accurate feasibility assessment is the key to the successful delivery of a clinical trial. The CRM’s feasibility team provides complimentary feasibility insights to study sponsors and CROs, which involves both pre-feasibility (country level enquiries) and full feasibility (study specific feasibility that would require site-level input) assessments.

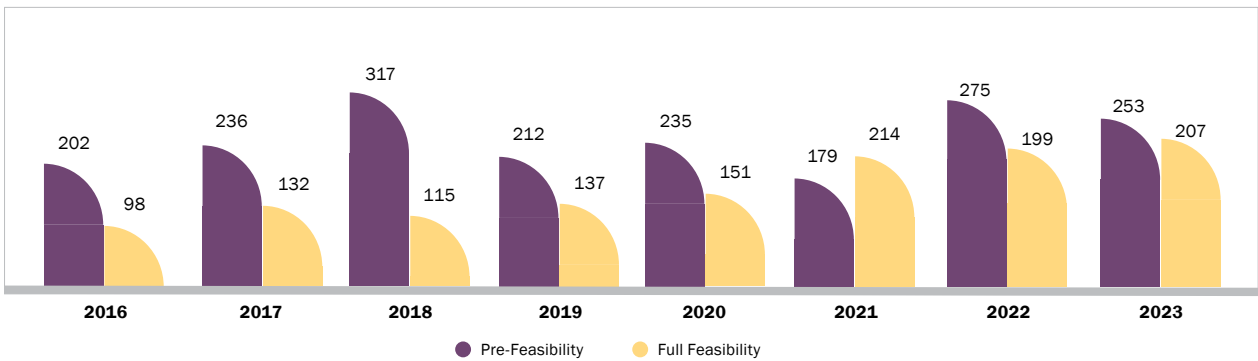


Figure 1: Pre-Feasibility & Full Feasibility from 2016 – 2023



Figure 2: Full Feasibilities received in 2023 by Therapeutic Area

Sponsored Research in Malaysia

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The significant increase in sponsored research conducted in Malaysia reflects the growing importance of the country as a destination for clinical trials. Since 2012, Malaysia has conducted a total of 2305 sponsored research, with 45% of these studies taking place in Ministry of Health (MOH) facilities, 41% in Ministry of Higher Education (MOHE), followed by 14% in private hospitals.

In 2023, Malaysia experienced its highest recorded number of sponsored research since the establishment of Clinical Research Malaysia, with a total of 276 studies conducted and 188 sponsored research were carried out in MOH facilities, which include state hospitals, district hospitals, and government clinics. The participation of various MOH facility sites in sponsored research is instrumental in facilitating patient access to innovative research treatments.

CLINICAL RESEARCH MALAYSIA

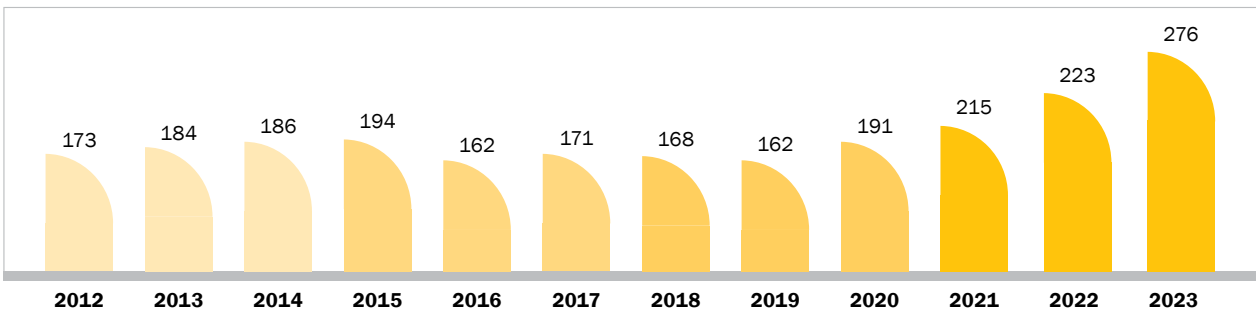


Figure 3: Number of Sponsored Research in Malaysia from 2012 - 2023

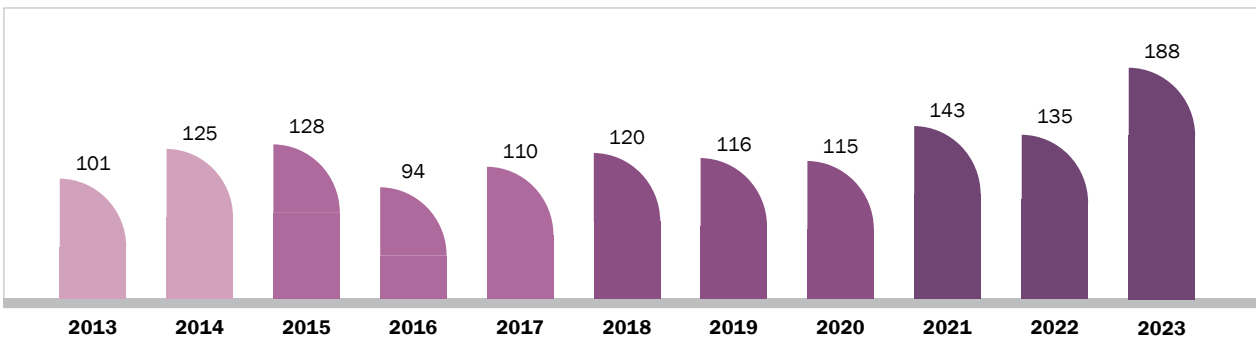


Figure 4: Number of Sponsored Research in MOH sites from 2013 - 2023

In Malaysia, like other developed nations, non-communicable diseases have become a major public health concern. Conditions such as cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes are among the examples of non-communicable diseases prevalent in the country. These diseases impose a significant burden on healthcare systems, emphasizing the need for innovative research and treatments to effectively mitigate their impact.

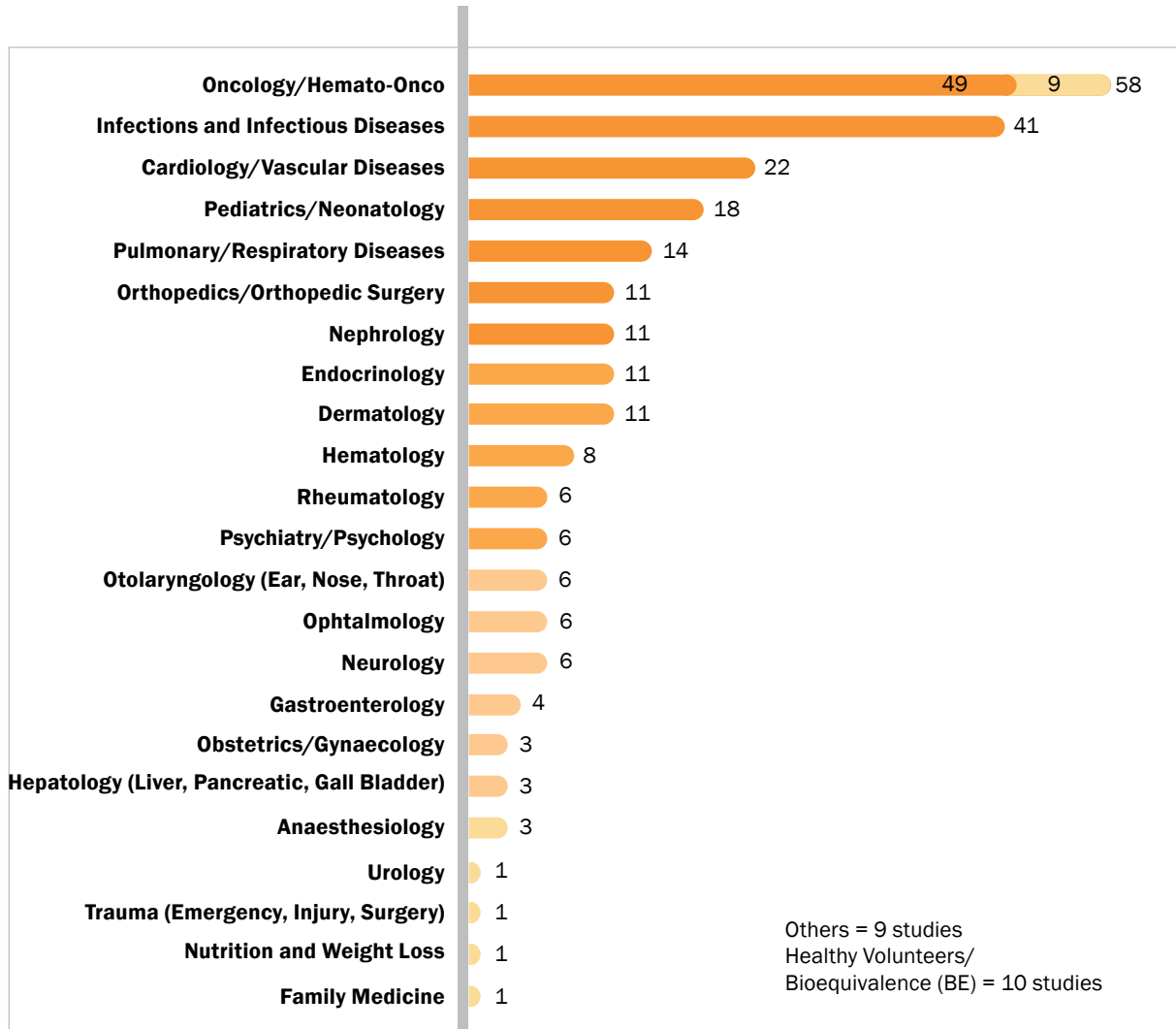


Figure 5: Number of Sponsored Research Conducted According to Therapeutic Area in Malaysia, 2023

Table 1: Trend of Top Therapeutic Studies, 2012 – 2023

THERAPEUTIC AREAS	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Oncology	23	15	18	24	15	18	18	25	32	33	37	49
Hemato-Oncology	2	2	2	5	3	1	1	5	1	7	9	9
Infections & Infectious Diseases	8	12	7	12	10	6	15	11	24	40	36	41
Cardiology/Vascular Diseases	10	22	20	21	18	28	20	14	13	11	20	22
Endocrinology	17	17	10	11	9	4	4	3	13	10	4	11
Pediatrics/Neonatology	8	9	4	8	6	7	8	13	6	13	12	18
Hematology	4	5	10	4	5	4	12	10	10	8	13	8
Neophrology	2	7	5	5	5	5	5	7	8	9	11	11
Pulmonary/Respiratory Medicine	8	4	4	5	6	6	5	8	3	5	9	14
Neurology	8	4	3	5	5	3	3	4	7	3	8	6

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CLINICAL RESEARCH MALAYSIA

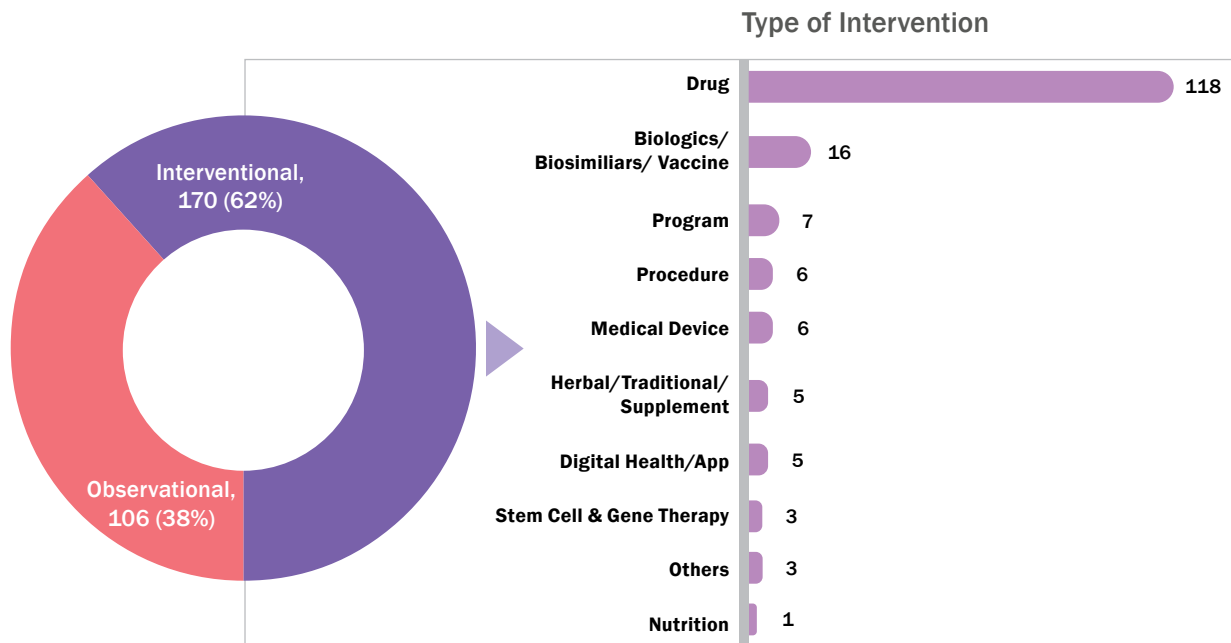


Figure 6: Breakdown of Studies According to Intervention, 2023

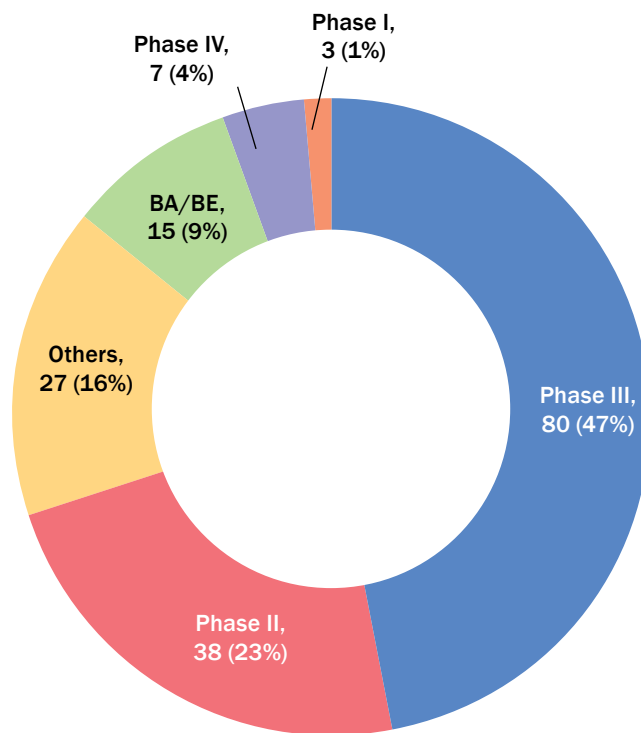


Figure 7: Phase Breakdown of Interventional Studies in Malaysia, 2023

Improving Access through Engagements

Under the **HUMANITY** principle, it is also essential to explore innovative research & development pipelines, especially when some of these lead to becoming first-in-class treatments and blockbuster drugs. In having these accessible at drug development stage in Malaysia, there needs to be active engagement with global industry and research leaders right from the early phase of R&D. In 2023 alone, CRM has engaged with over 100 organisations, with some of these engagements having converted to successful feasibility approaches and new studies.

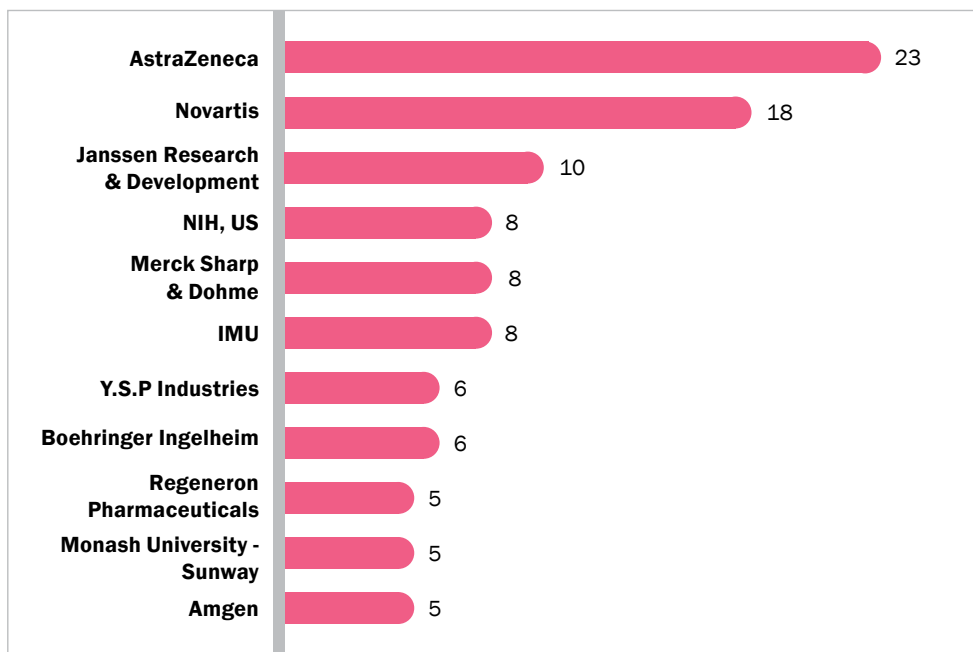


Figure 8: Top Contributors in Number of New Sponsored Research by Sponsors for 2023

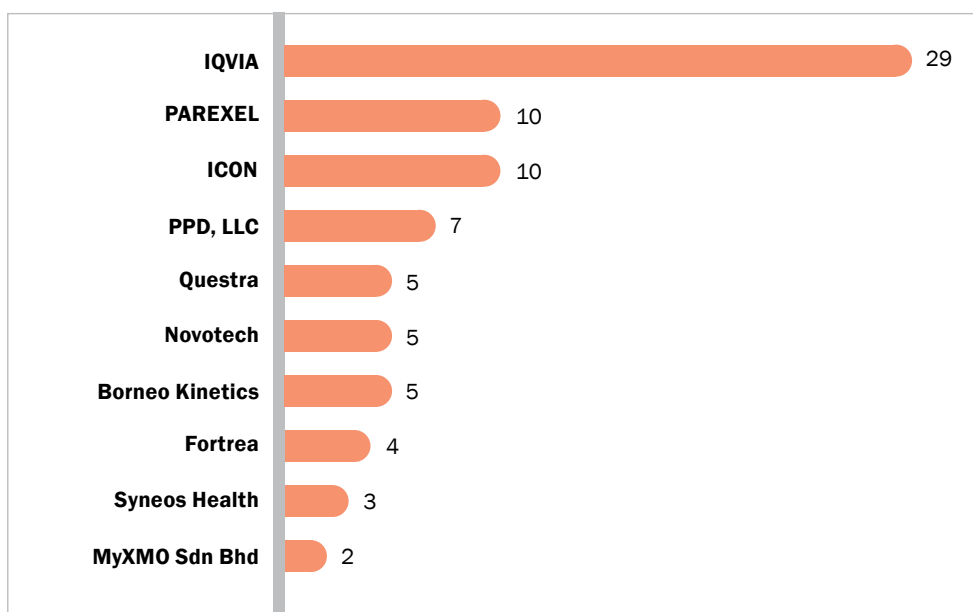


Figure 9: Top Contributors in Number of New Sponsored Research by CROs for 2023

HUMANITY

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CLINICAL RESEARCH MALAYSIA

In addition, through CRM's participation in some of the renowned scientific gatherings and meet, the team focuses its effort to network, and keep a pulse on the latest innovative treatments available. One of the key events is ESMO Congress 2023, in Madrid, Spain that had CRM along with Head of Oncology & Radiotherapy Speciality in MOH Dr Ros Suzanna Bustamam (Kuala Lumpur Hospital) engaging with the top management of several global pharmaceuticals including Astra Zeneca, Roche & BeiGene. Malaysia's good track record and clinical research accomplishments were also highlighted during these meetings, and outcome from this saw new study opportunities to Malaysia, including of early phase and of new therapeutic areas.

In addition, CRM was also given podium opportunities in several international meets/ conferences, sharing on Malaysia's value proposition in sponsored clinical research to the global audience. Some of the few international engagements CRM spoke in are as follows:



DiA China 2023 in Suzhou, China



CRGo World Conference 2023 in Hong Kong



REACTA Forum in Chiba, Japan



DIA Asia 2023 in Beijing, China

Accelerating Malaysia in Global Clinical Trials

To further showcase the accomplishments and achievements of sponsored research in Malaysia, CRM organized its 2nd CRM Trial Connect, following its inaugural success in 2022. Attended by over 500 delegates, exhibitors and faculty members, the 2-day conference has once again gained positive traction from crowds consisting of 105 organizations with 12 participating countries. The conference was aimed in showcasing Malaysia's capabilities, experiences and outstanding achievements in multinational clinical research and sponsored clinical trials.

In conjunction with Clinical Trials Day celebration, the conference also saw the Sponsored Research Awards (SRA) to celebrate all our diligent, motivated and passionate investigators as well as clinical trials site staffs, sponsors, CROS and patients during the opening ceremony. We truly believe that these efforts are what collectively bridging the gaps of unmet needs of this field as the conference highlighted some of the most exciting sharing by our top investigators and sites.



Driving Community Awareness

Clinical Research Malaysia have been active in work of awareness to the public, especially through the I AM AWARE (IAA) campaign and the Find A Clinical Trial (FACT) Platform. The IAA campaign which was initiated since 2017, is aimed to drive awareness among the public on clinical trials in Malaysia, and addressing common misconceptions by the public about clinical trials. Seven physical roadshows were conducted under the IAA campaign at hospitals and primary care centre throughout the country, to engage with the local community, addressing on clinical trial awareness. In addition, social media was used as a wider outreach tool to the public, sharing on facts about clinical trial.

With 40,000 followers (a 14% increase since 2022) across all CRM's social media platforms and over 58 million in impressions gathered in 2023, CRM values the social media as an effective tool in engaging with the public in terms of sharing pertinent updates and information pertaining to clinical trials. CRM social media platform is also the driving force behind CRM's clinical trial advertisement service, to help boost recruitment numbers of studies through online reach.



The FACT platform is another initiative driven by CRM to enable the public to access information pertaining to clinical trials by on disease condition. In addition to knowing relevant clinical trials near their vicinity, viewers are able to register their interest with the sites, for them to be contacted for more information pertaining to the trial. In 2023, the platform had over 170 people registering their interest, spanning over 30 disease conditions.



HUMANITY

Work-life Balance

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Achieving a healthy work-life balance is essential for employee's overall well-being, job satisfaction, and productivity. With the aim of providing opportunities for staffs to engage in sports, physical activities, and recreational pursuits, CRM Sports and Recreational Club (SRC) actively promotes such activities all year round. In the year 2023, the club has organised different events such as Movie Night, Buka Puasa Gathering, CRM 2023 Gala Dinner as well as an exciting day in ESCAPE Petaling Jaya



Consistency in Achieving KPIs

The value of **STABILITY** is reflected in our consistency in delivering the organization's Key Performance Indicators (KPIs) in continuing to grow sponsored research within the country. Every year, CRM ensures the key metrics set at the beginning of the year are met, and the year 2023 surpassed all expectations with the highest ever accomplishments in terms of new sponsored studies, with a marked 24% growth from the year before. This excellent delivery has put Malaysia back to 2nd in Southeast Asia in number of new sponsored research (as per data from clinicaltrials.gov). CRM has contributed significantly to the growth of clinical trials in the country, thereby generating more jobs in this field and creating career pathways for people who wish to advance their careers in the clinical research field.

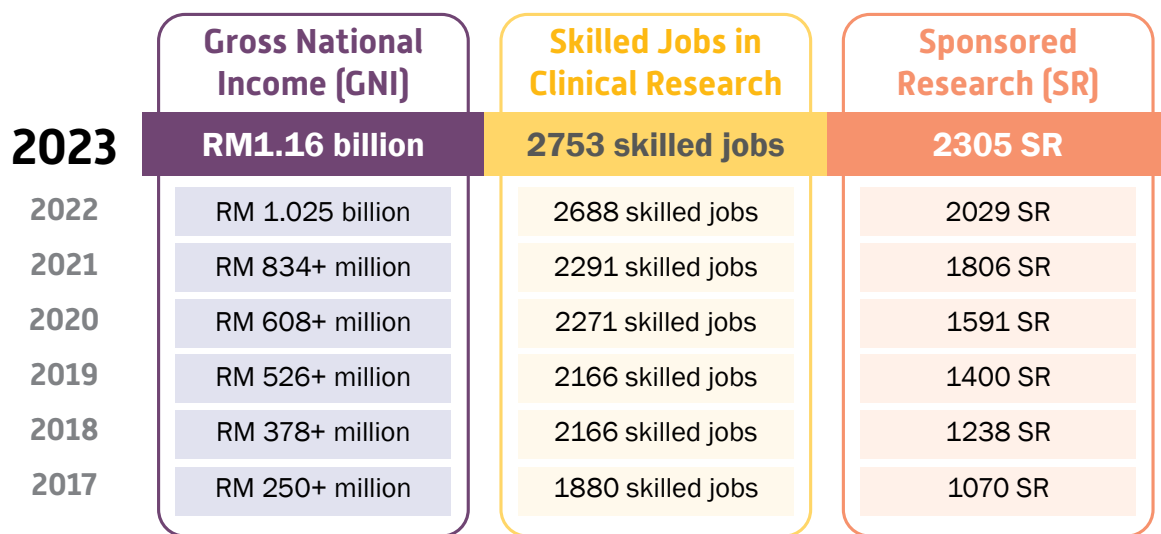


Figure 10: KPI Scorecard from 2017 - 2023

Clinical Research Sites

Overall, the number of clinical research have increased by over 80% since 2016, with now almost 260 centres in Malaysia having had conducted clinical research. Majority of the sponsored research are in MOH trial sites. However, there has been a significant uptake for sponsored research across university hospitals and private centres over the years, with each sector growing in tandem. Much of this is owed to these sites having focused on building their clinical research capabilities and experience in conducting global sponsored clinical research. In addition, there is also a need to sponsors to expand their trial site selection to different sectors as per the standard of care and line treatment received by patients at these centres, to meet the inclusion/ exclusion criteria defined by the study.



STABILITY

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CLINICAL RESEARCH MALAYSIA

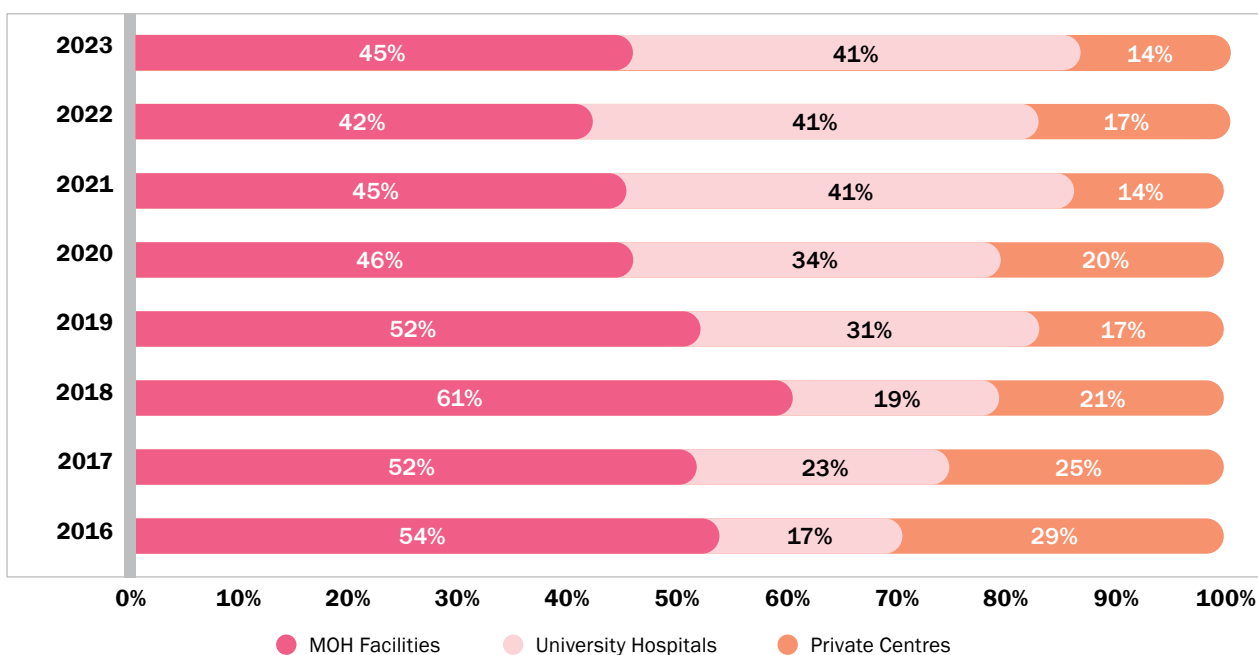


Figure 11: Distribution of Sponsored Research Between Different Site Sectors (2016 – 2023)

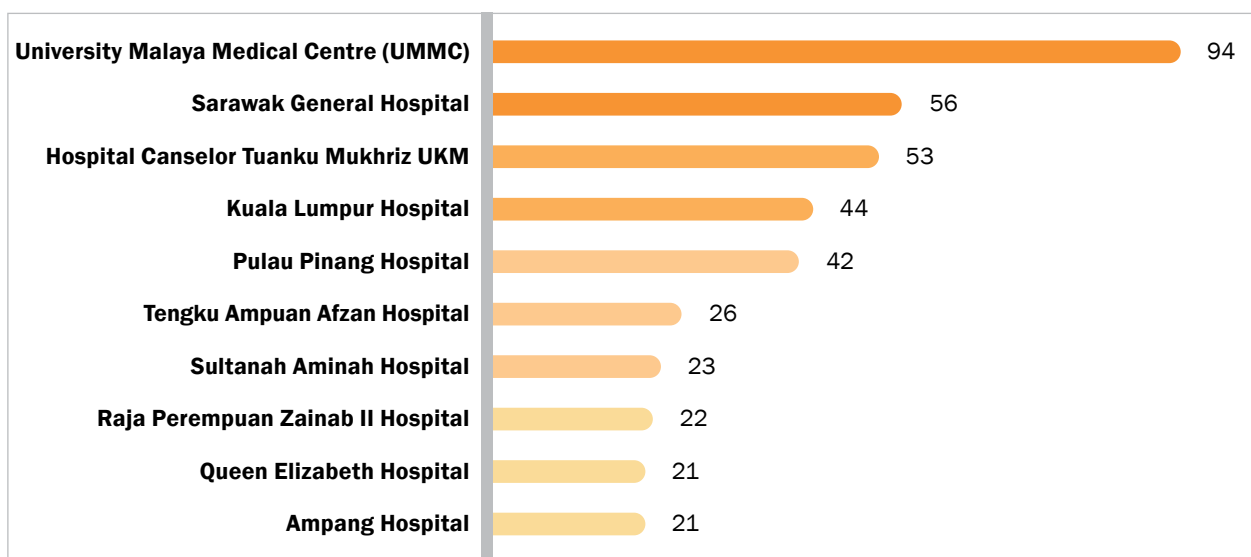


Figure 12: Top Sites Awarded with New Sponsored Research in 2023

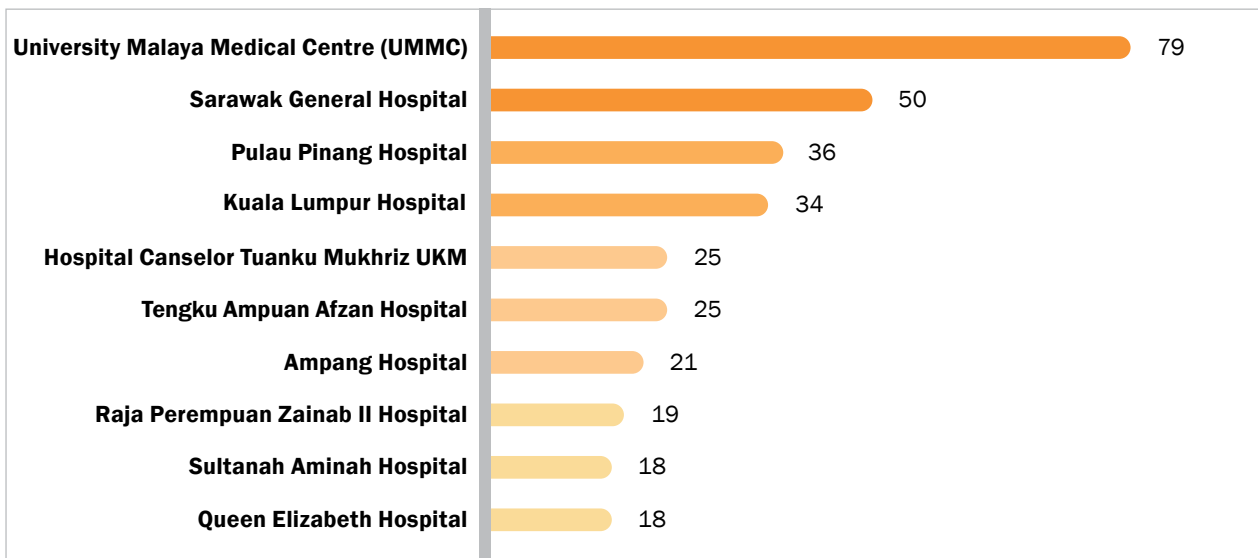


Figure 13: Top Trial Sites Based on New Interventional Sponsored Research in 2023

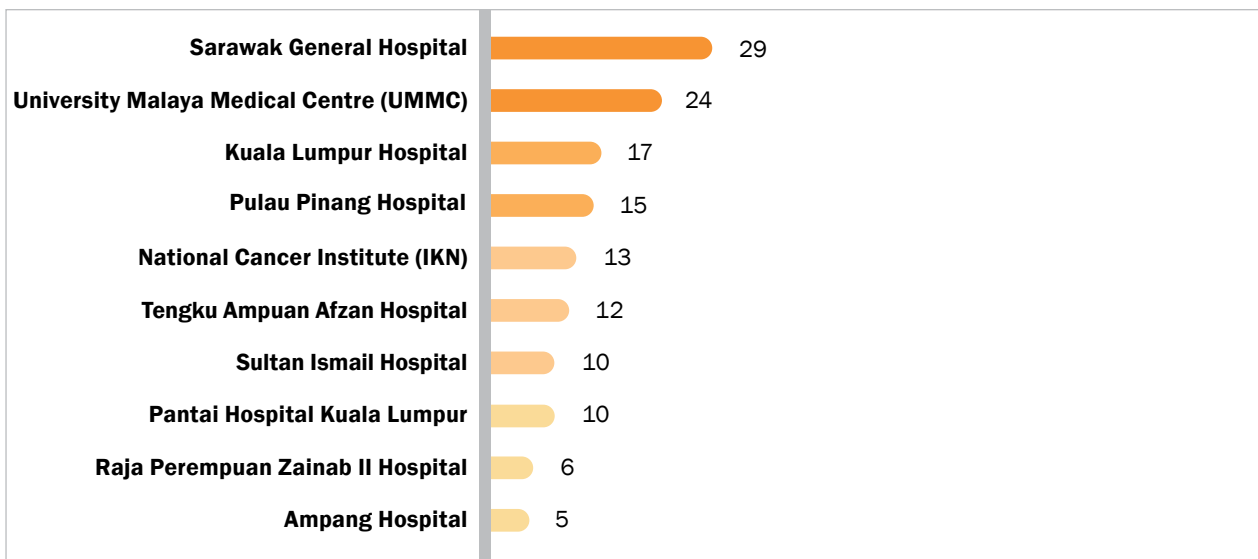


Figure 14: Sites with Highest Number of Onco/ Hemato-Onco Trials approved in 2023

Site Recruitment Achievement

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In 2023, at least 8 trial sites have received distinction by the study sponsor for delivering well in the recruitment of the global sponsored studies participated. These include Top Global Recruiter as well as Global and Regional First Recruiter. Top mentions include Sarawak General Hospital, Institute of Respiratory Medicine and Tengku Ampuan Afzan Hospital.

In addition, CRM monitors internally the recruitment activities of studies that are managed by CRM Study Coordinators. In 2023, the average recruitment rate noted 94%. This is an element of **STABILITY** that CRM has consistently and reliably delivered to meet the recruitment target and expectations.

CLINICAL RESEARCH MALAYSIA

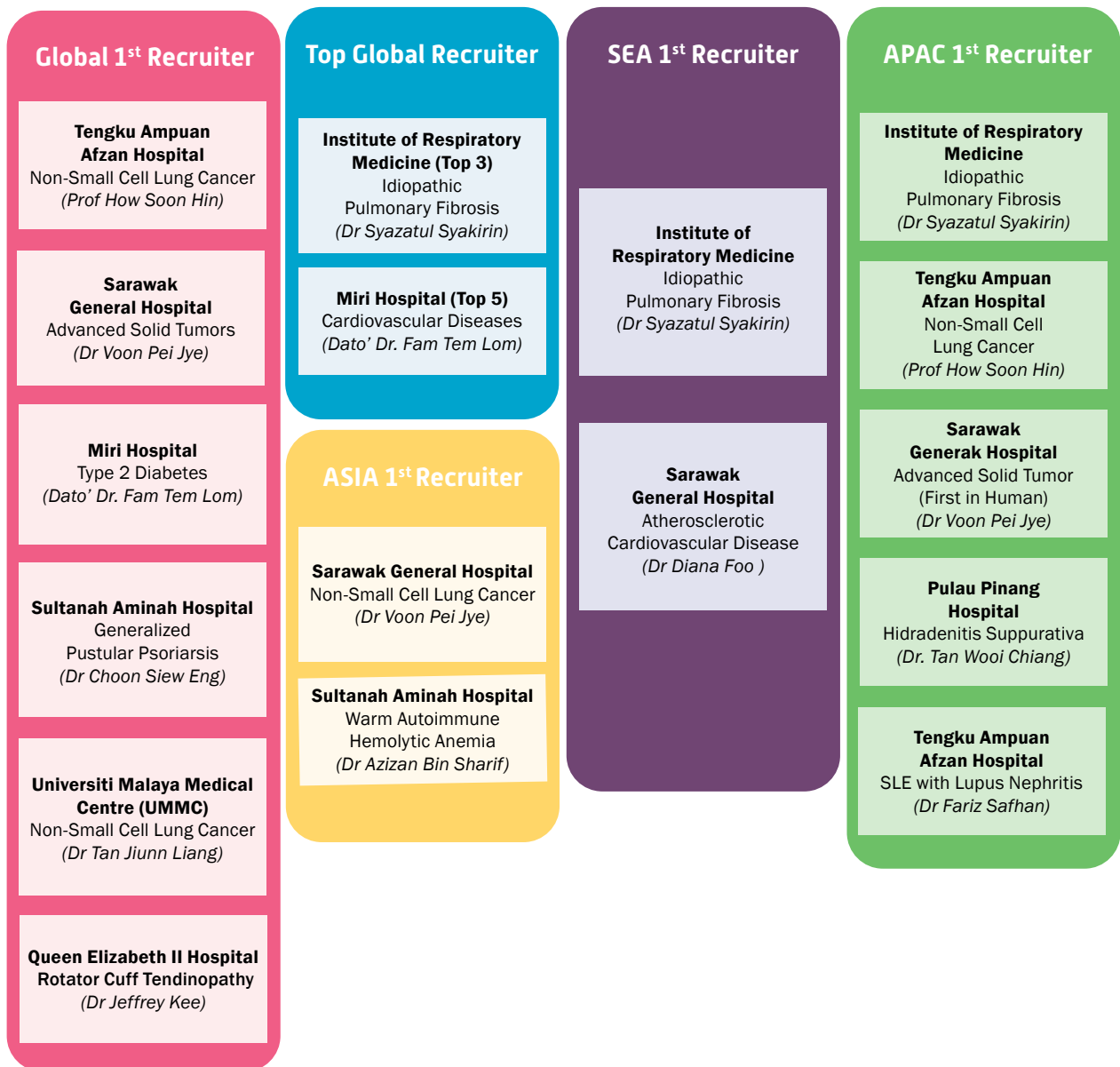


Figure 15: Site Recruitment Achievement in Global Trials, 2023

CRM 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. The company has also implemented several measures to create new business opportunities, and this include provision of services for study material destruction as well as clinical trial recruitment advertisement. Since 2020, CRM's income has exceeded its expenses, and the year 2023 is no different. This further establishes CRM's business as efficient and self-sufficient in generating its own capital and operational expenditure.

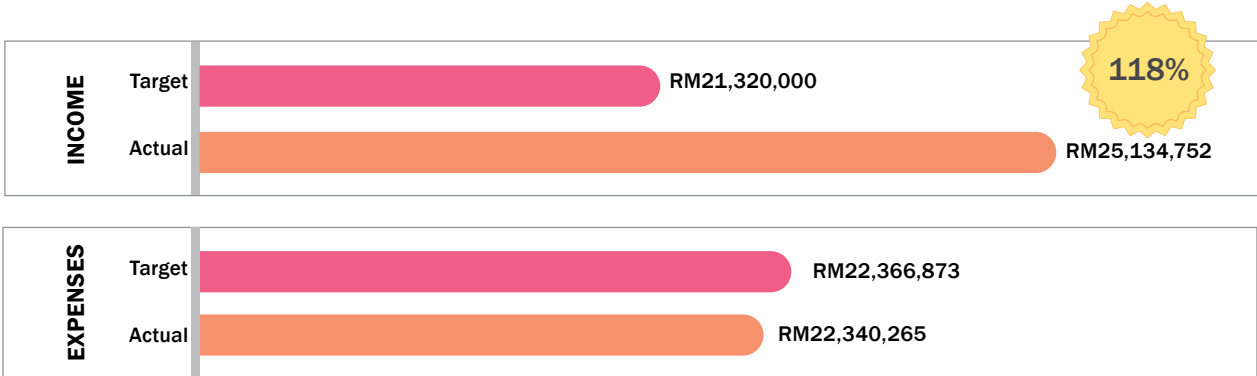


Figure 16: Clinical Research Malaysia Finance Performance in 2023

As a Site Management Organization that manages the study budget for Ministry of Health trial sites, the number of invoices issued by CRM has been growing since 2012. Cumulatively, CRM has issued a total of 24,849 invoice to sponsors and CROs with a total amount of over RM 430 million.

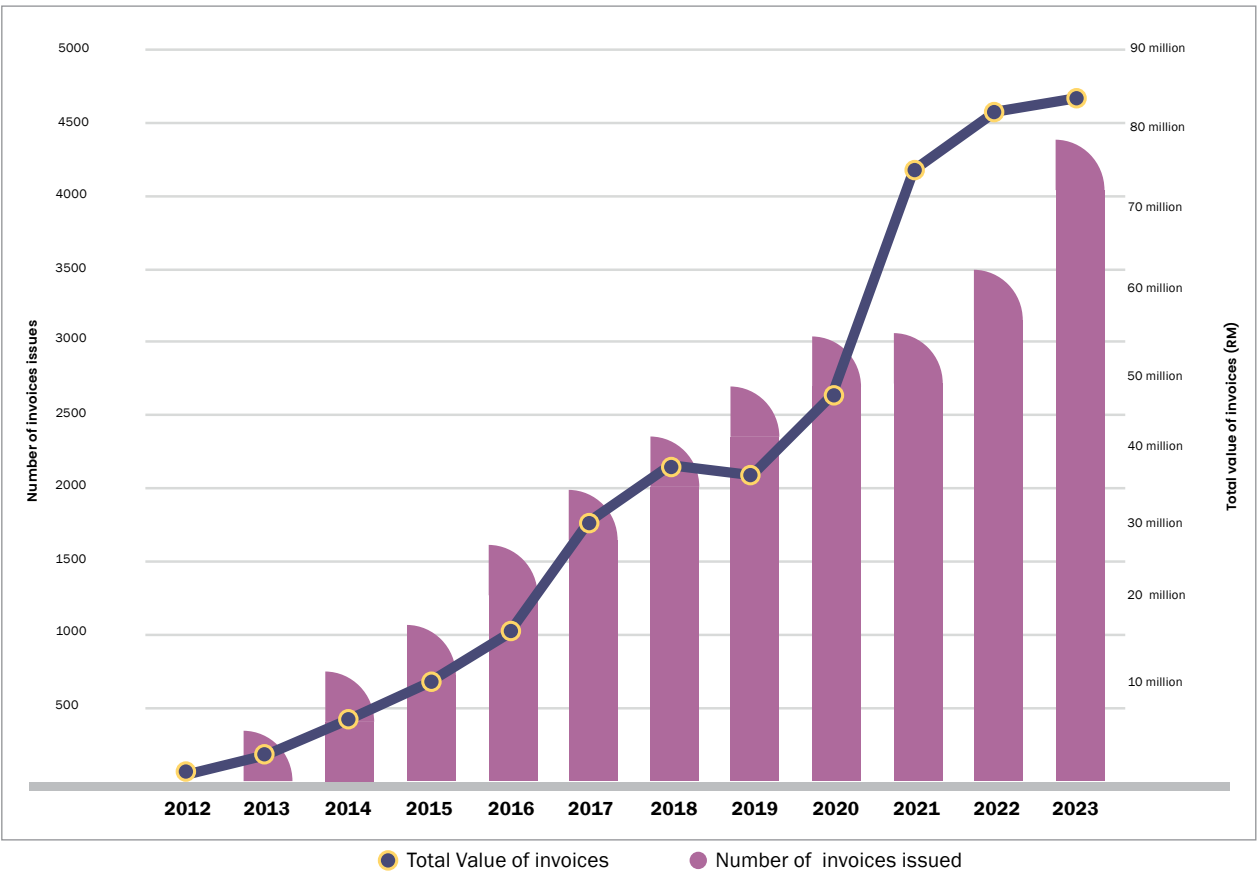


Figure 17: Invoices Issued by CRM between 2012 and 2023

STABILITY

Investing in Human Capital Development

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Through the element of **STABILITY**, CRM believes in creating professionals in clinical trial management that can deliver studies with Speed, Quality and Reliability. This is done by continuously investing in improving the capabilities of its Study Coordinators (SC) through the various training programmes carried out throughout the year. As CRM is a learning organization that prioritizes personal and professional growth, upskilling and expanding knowledge in this field is an important element that CRM upholds.

Table 2: Training and Development Programs in 2023

ORGANISED	PARTICIPATED
Training to Improve Performance of SC (TIPS): Train The Trainer	DIA Annual Meeting
TIPS for Study Coordinators	DIA-CoRE Singapore
Patient Recruitment and Retention Workshop	ESMO Congress
Preparation for Regulatory Inspection Workshop	ASCO Annual Meeting
Protocol Compliance Workshop	REACTA Forum
GCP Refresher Workshop	ASCOMOS

STABILITY is also in creating a clear career development path for those who are interested to grow in this field. This is done through developing CRM line managers and having succession planning in place. Apart from this, CRM also offers Education Grant for CRM's employees who wishes to obtain an additional or higher degree in the field of their choice.

There has also been a 11% growth in the number of SC compared to the year before and this is in tandem to the growing number of sponsored research conducted in the country. All of CRM's SC are GCP certified, have undergone the necessary internal company SOP trainings, and are placed in most of the active MOH trial sites throughout the country, including some private hospitals.

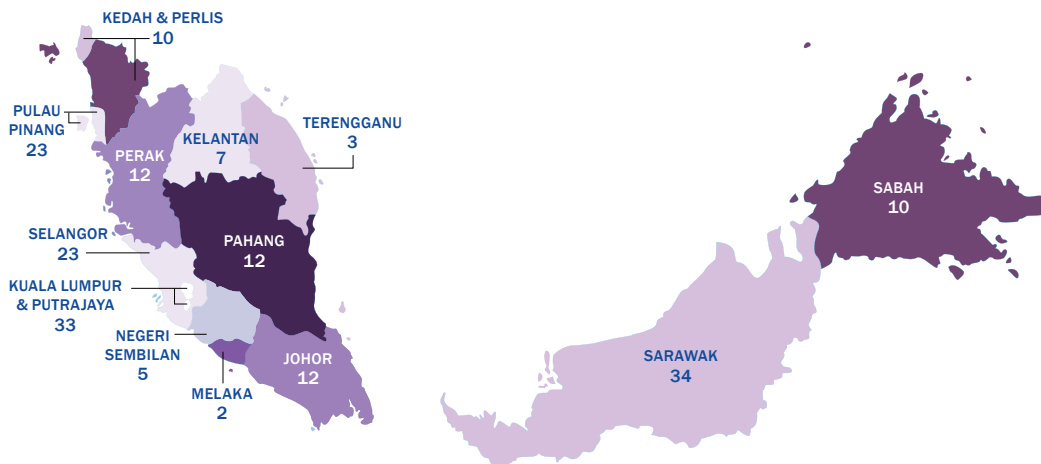


Figure 18: CRM Placement of Study Coordinators in 2023

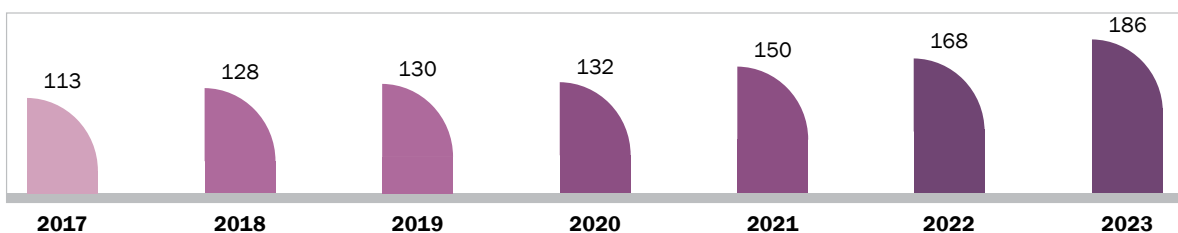


Figure 19: Growth of number of CRM Study Coordinators from 2017 - 2023

Early Phase Accomplishments

Early phase research in Malaysia accomplished significant milestones in 2023. First and foremost was Sarawak General Hospital (SGH) conducting the very first First-in-Human study in the country, led by Principal Investigator (PI), Dr Voon Pei Jye. Not only did the study team performed in trial participant recruitment (SGH was 1st site within APAC to enroll a trial participant), but also due to its active efforts in conducting the study, the PI was recognized as one of the co-authors in study findings that was presented in the esteemed International Conference 2023 hosted by the European Organisation for Research and Treatment of Cancer (EORTC), the National Cancer Institute (NCI), and the American Association for Cancer Research (AACR) in Boston later that year.



Hospital Ampang, as the other accredited FIH study site in Malaysia also had attained significant achievement in being awarded a First-in-Patient study, the first for its facility. The hematology study was initiated in November 2023 and is led by Dr Veena Selvaratnam as the Principal Investigator.

Efforts are also ongoing by CRM spearheading its Phase 1 Realization Project 2.0 which is well in its second year. Under capability development, in effort to create research teams that are capable in conducting early phase clinical research, CRM have engaged with several globally renowned early phase institutions to explore opportunities to send investigators and study coordinators for hands-on training in phase 1 trials. Following CRM close collaboration with Princess Margaret Cancer Centre (PMCC), CRM was invited to participate in their Global Partners Consultation Program in October 2023. The program provided excellent opportunity to connect with some of PMCC's partners including Peter MacCallum Cancer Centre in Melbourne, Australia. Engagements are currently ongoing with the Clinical Trial Unit of this center, exploring fellowship opportunities in early phase.

SUSTAINABILITY

Global Trusted Research Management Organisation

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CRM recognizes the importance of **SUSTAINABILITY**, and hence staying aligned as a Global Trusted Research Management Organisation (GTRMO) is key in ensuring our role as an organization with high integrity and that produces quality services. CRM's guiding principle steers the organization in ensuring that CRM's long-term value creation is achieved with core values, code of conduct and key strategies in place and embedded in all its people. In addition to staying accredited with both ISO Quality Management System and Anti-Bribery Management System standards, CRM has also developed its Organisation Anti-Corruption Plan which serves as a strategic document for the implementation of governance processes within CRM.



SUSTAINABILITY

Next 10-year Plan

In July 2023, CRM had its first Strategic Meeting involving its board members as well as its management. The objective was to map the next decade of CRM as a conducive and sustainable organization. Following this, three key missions were identified to drive Malaysia as a preferred hub in Asia. To ensure CRM remains on track in its vision and missions, several Key Performance Indicators were set as part of its 2033 goal, which are as follows:



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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

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