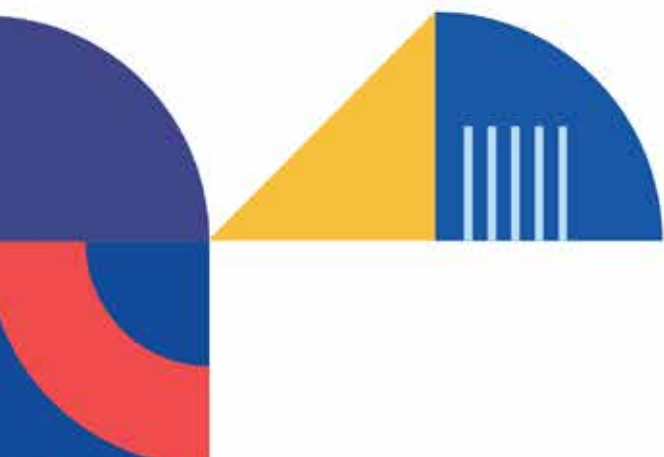




2022

ANNUAL REPORT



ABOUT OUR REPORT



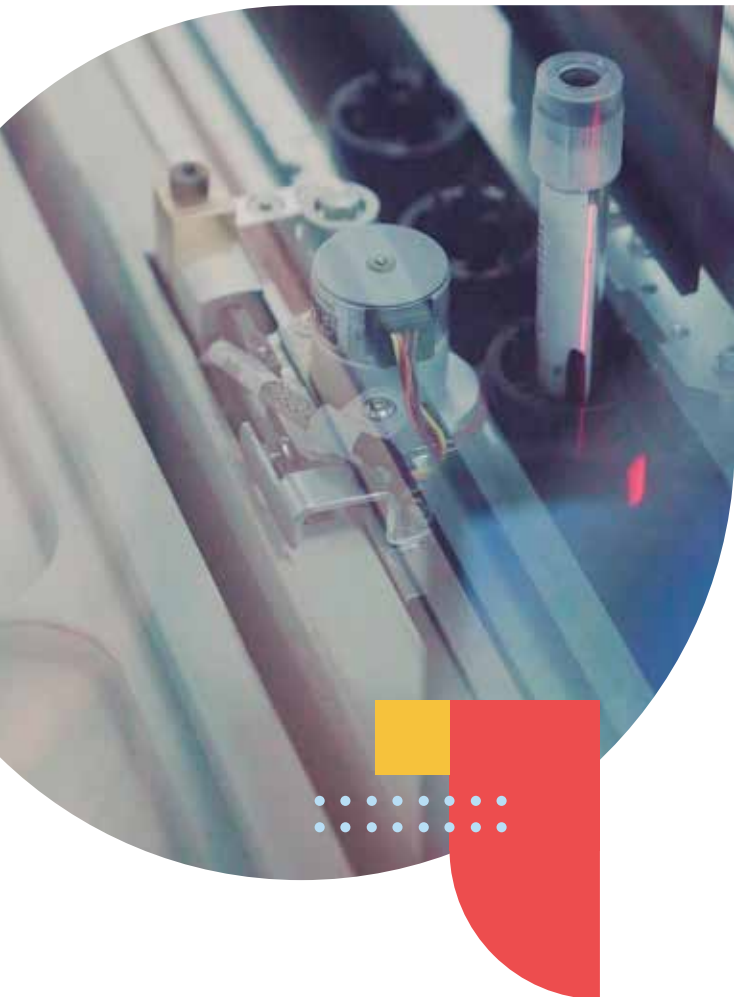
Clinical Research Malaysia (CRM) is proud to share our achievements and success stories in this 2022 Annual Report. We encourage our stakeholders, industry partners, investigators and members of the community to take a moment to read our 7th annual report, which contains information about the important 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**).

INSIDE THIS REPORT

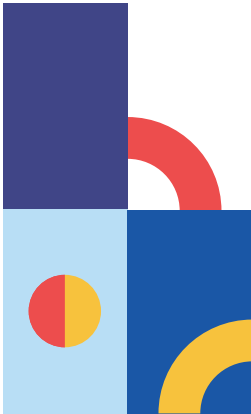


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FOREWORD

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CLINICAL RESEARCH MALAYSIA

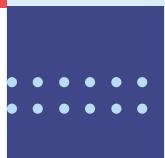


Following post-Covid-19 era, year 2022 was the year CRM continues to pick up the pace to remain at the forefront of the current global trends and progress in clinical research. It was a busy year indeed for CRM, and this is reflected in the Gross National Income (GNI) for the country's clinical research industry with a total of RM1.025 billion since the year 2012. Ultimately, the delivery of trials with speed, quality and reliability will become a point of rectification for stakeholders' confidence in choosing CRM as their one stop center, thus attracting more sponsored research into Malaysia.

This opportunity calls for the welcoming of the new Minister of Health on board, YB Dr Zaliha Mustafa. A hearty congratulations to the newly appointed minister and as the Chairperson for our board of directors as well. Looking back, there are many of the achievements that CRM has accomplished with the hard work of its employees all over Malaysia. Our biggest pride of 2022, the CRM Trial Connect conference where it served as a platform for networking, and it was a huge success amongst stakeholders on top of placing CRM's name on the global map.

Finally, I would like to thank everyone in Clinical Research Malaysia for their continuous commitment and perseverance in the journey of making CRM the Global Trusted Research Management Organization. As we embark on 2023 journey, CRM will continue to strive towards operational excellence, growing ISR, and improving the quality of services all while remaining true to our three (3) guiding principles which are **HUMANITY, STABILITY** and **SUSTAINABILITY**.

Dr. Akhmal Yusof
CEO, Clinical Research Malaysia



BOARD OF DIRECTORS



YB Dr Zaliha Mustafa

Minister of Health, Malaysia



**YBhg. Tan Sri Dato'
Seri Dr. Noor Hisham**

*Director General of Health,
Ministry of Health, Malaysia*



**YBhg. Dato' Zamzuri
Bin Abdul Aziz**

*Deputy Secretary General
(Finance), Ministry of Health,
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Hassan**

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



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A. Rahman A. Jamal**

*Founding Director, UKM Medical
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University Kebangsaan Malaysia*



**Prof. Dr. Abdul Rashid
Abdul Rahman**

*Medical Director and Senior
Consultant Physician, An Nur
Specialist Hospital*



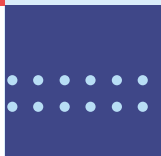
**YBhg. Dato' Haji Zein
Isma Bin Haji Ismail**

Professional Actuarist



Mr Ewe Kheng Huat

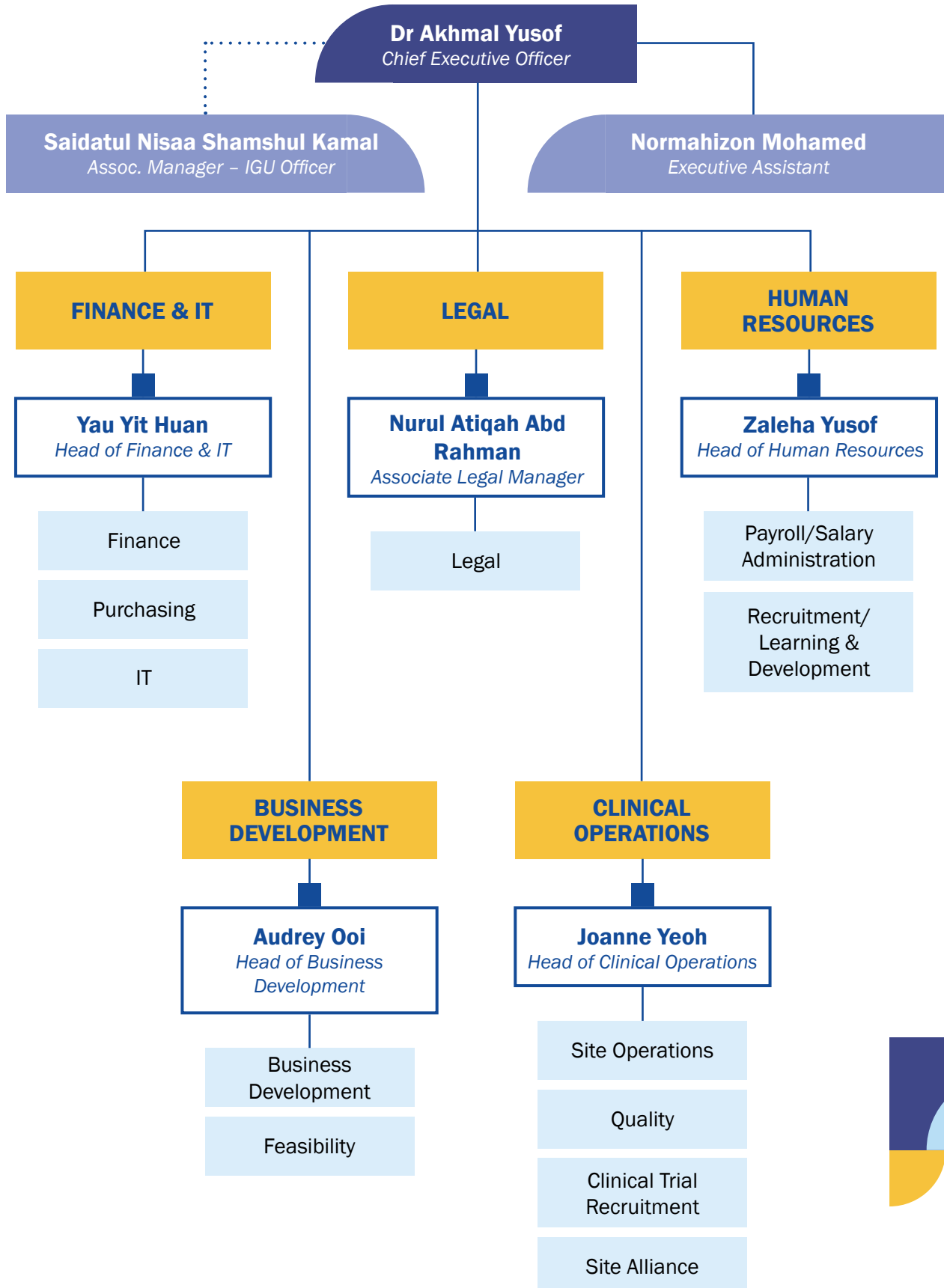
*Former Executive Director of the
Pharmaceutical Association of
Malaysia (PhAMA)*



ORGANISATION CHART

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CLINICAL RESEARCH MALAYSIA





ABOUT CRM

VISION

To make Malaysia the preferred 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 Material 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.



CRM'S GUIDING PRINCIPLES

CRM'S Guiding Principles

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Clinical Research Malaysia has come a long way since the establishment of the company in year 2012. Throughout its journey, CRM has achieved so much by staying true to its vision and core values. It is vital to have a solid foundation that enables the organisation to thrive even through unprecedented times and to further advance in this field. Reflecting on the journey undertaken, and moving forward to what's next, CRM's path remains rooted to its three (3) guiding principles which are **HUMANITY**, **STABILITY** and **SUSTAINABILITY**.



HUMANITY

- Meeting unmet medical needs through clinical research
- Raising public/ patient awareness & engagement
- Corporate social responsibility & work life balance

- Steadfast in clinical research initiatives
- Consistency in clinical research performance
- Continuous engagement with stakeholders
- Human capital development



STABILITY



SUSTAINABILITY

- Globally trusted research management organisation
- Operational excellence & vision 2026
- Organisational culture that practices good governance & adherence to code of conduct



Meeting Unmet Needs through Clinical Research

One of the main drivers in bringing in clinical trials into the nation is to provide early access of research treatment for patients who are especially in need and have exhausted all other forms of treatment. Through participation in clinical trials, trial participants are supported in healthcare and treatment to ensure available standard of care is provided in addition to the research treatment that is being given.

Feasibility studies are the gateway to bringing in more clinical trials to Malaysia. It is not only a tool for study sponsors to assess whether a trial is possible to be conducted in Malaysia, but is also a method for Malaysia to promote capable yet unknown sites and investigators. Accurate feasibility is the start towards delivering a successful clinical trial, and recognising that, the CRM's feasibility team supports in providing feasibility insight to study sponsors and CROs. This complimentary service includes pre-feasibility (country level enquiries) and full feasibility (study specific feasibility that would require site-level input).

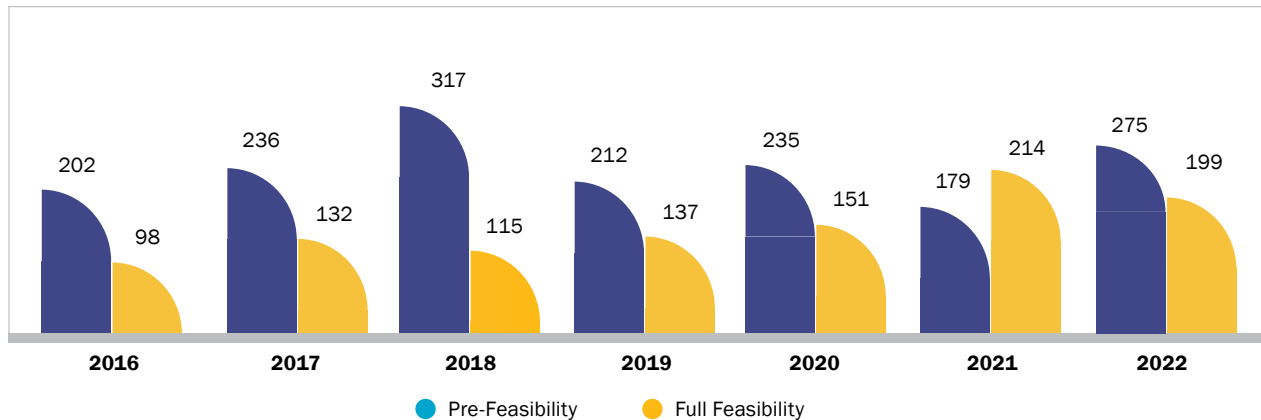


Figure 1: Pre-Feasibility & Full Feasibility from 2016 – 2022

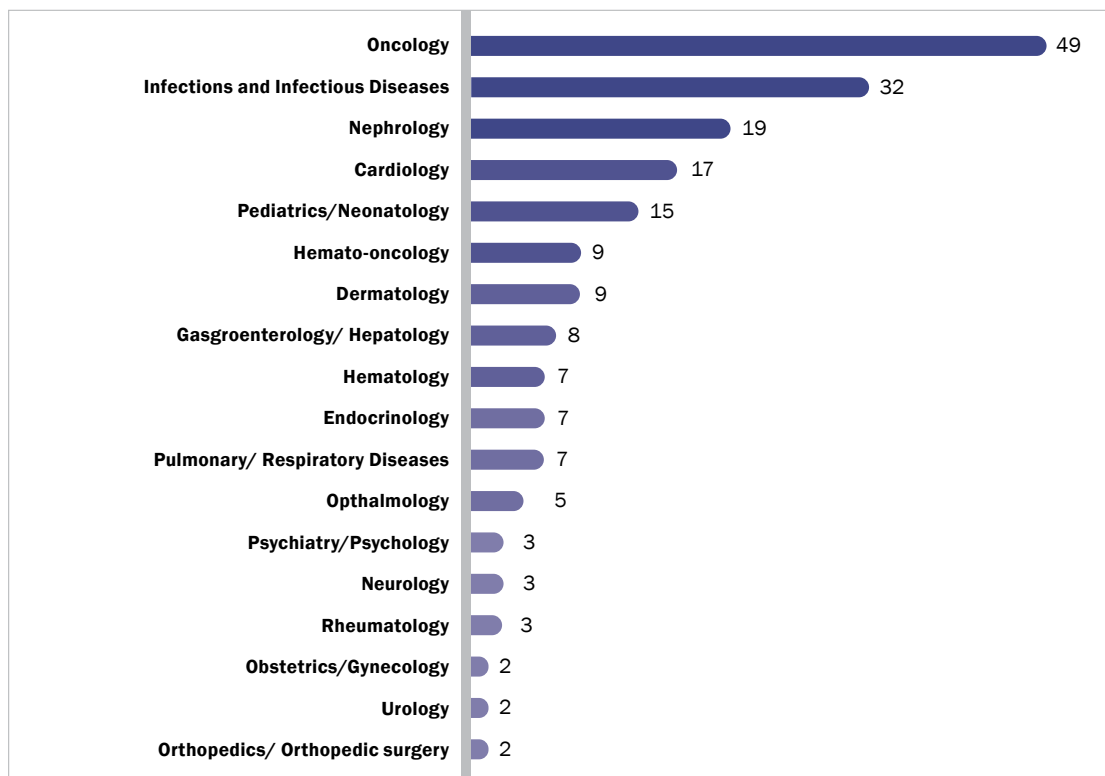


Figure 2: Full Feasibilities received in 2022, by Therapeutic Area

Since 2012, the country has conducted 2029 sponsored research, with 223 sponsored research just in 2022. Over 60% of these studies are conducted in Ministry of Health (MOH) facilities, including state hospitals, district hospitals and government clinics, enabling the pathway for majority of patients to participate in clinical trials that access novel innovative research treatments.

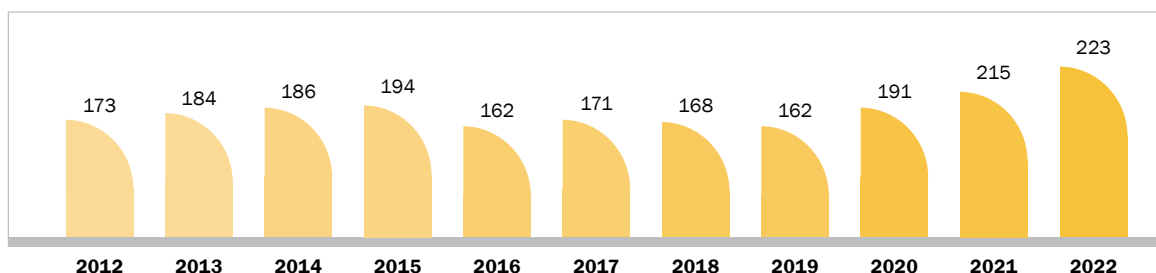


Figure 3: Number of Sponsored Clinical Research from 2012 – 2022

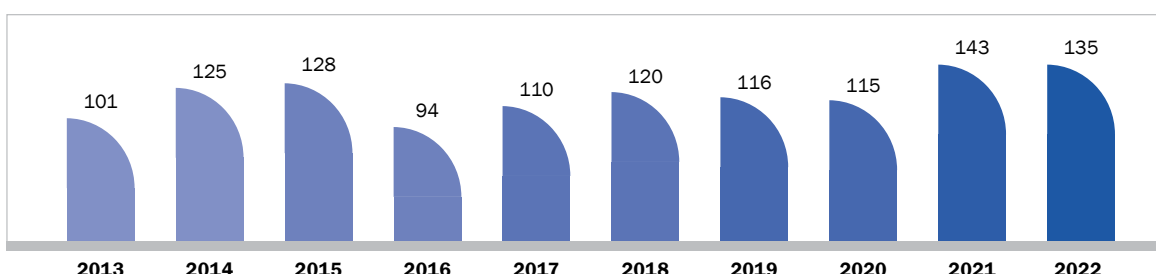


Figure 4: Number of Sponsored Clinical Research in MOH facilities from 2013 – 2022

Similar with developed nations, Malaysia too have unmet needs in managing non-communicable diseases. With cardiovascular disease being the leading cause of mortality, and diabetes and cancer contributing to high burden to the healthcare sector, there is need to bring in more innovative research treatments to address the management of these conditions.

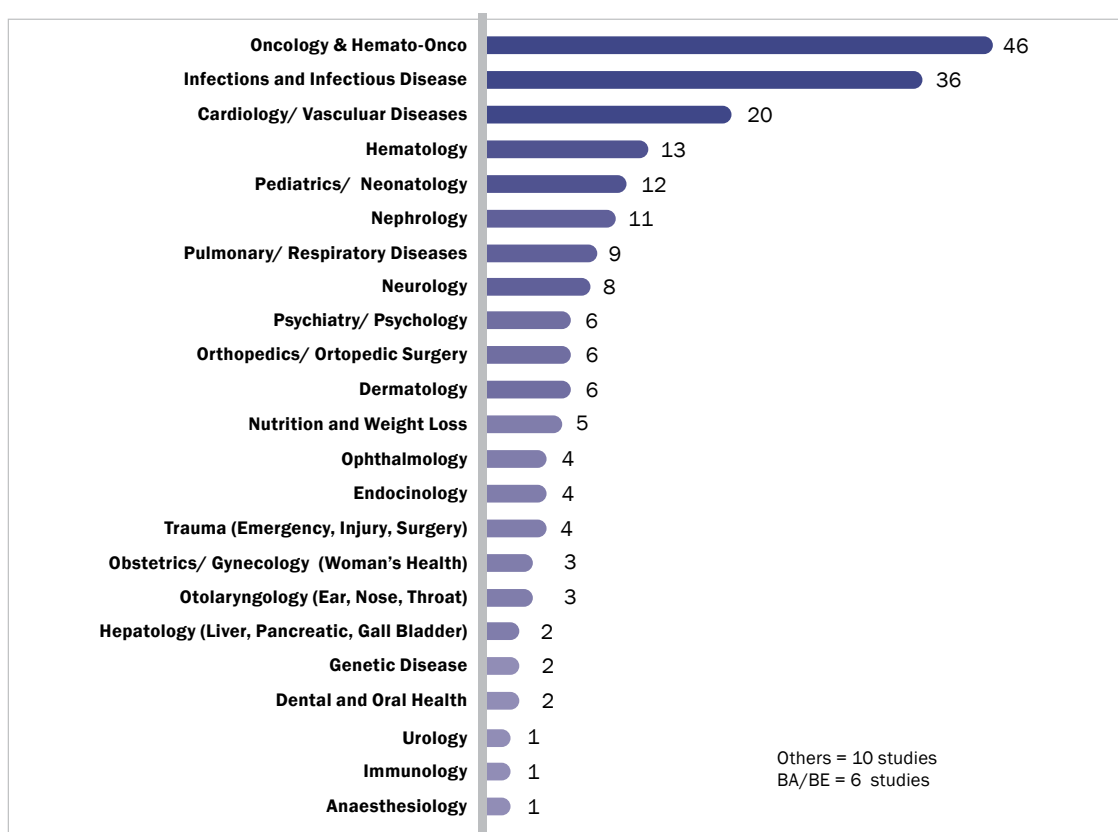


Figure 5: Sponsored Research according to therapeutic area in Malaysia, 2022

Table 1: Trend of Sponsored Research by top therapeutic areas in Malaysia, 2012 – 2022

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

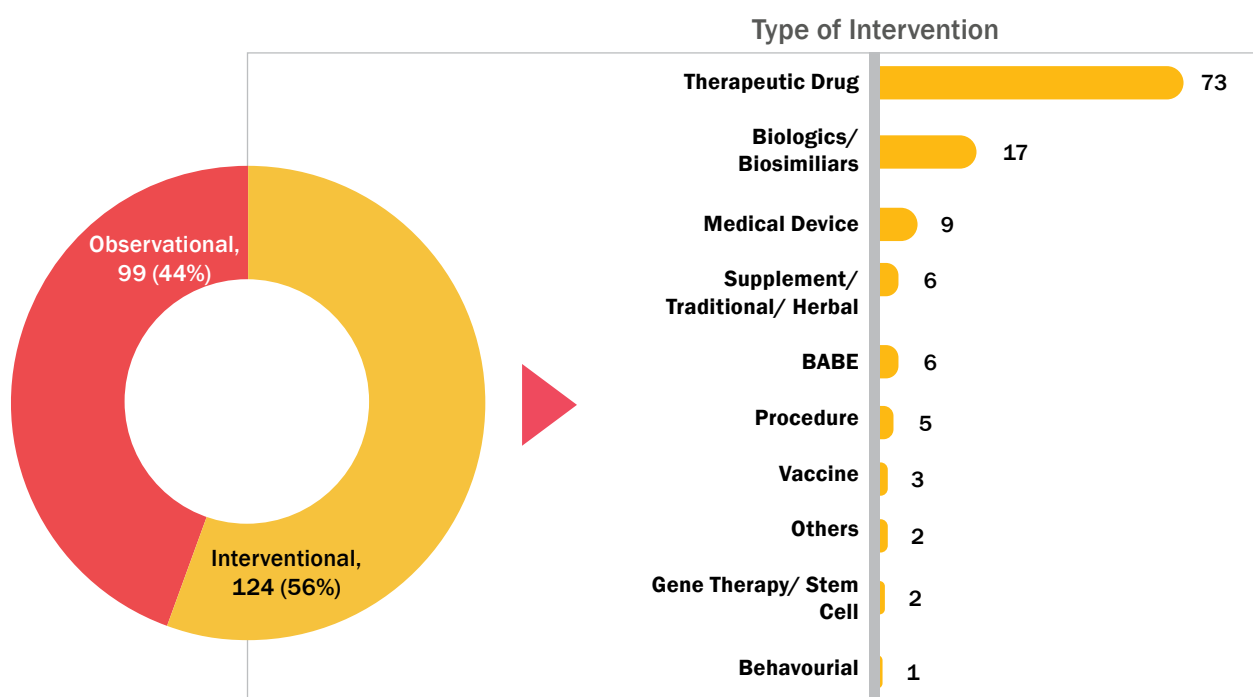


Figure 6: Breakdown of type of sponsored research in 2022 & classification of intervention types

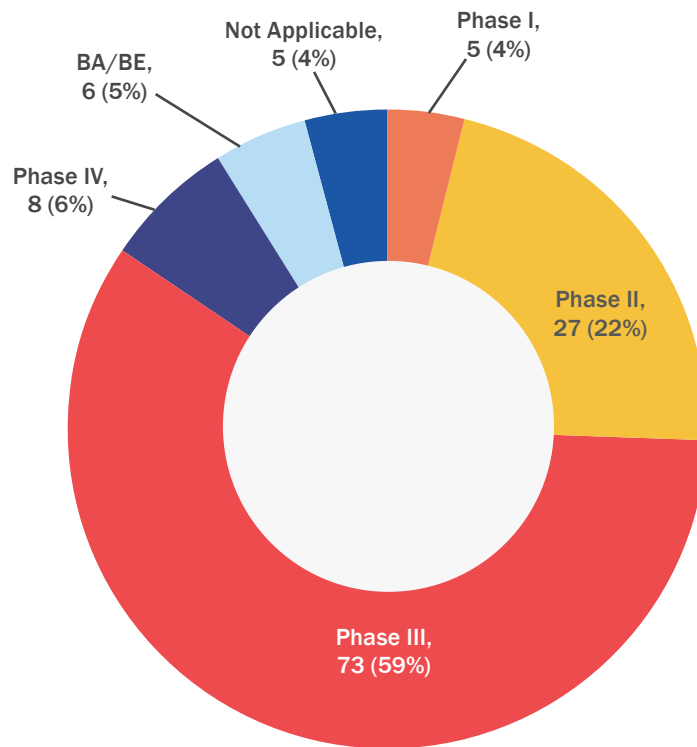


Figure 7: Phase breakdown of interventional studies in 2022

Gaining Exposure & Partnership

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. 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.

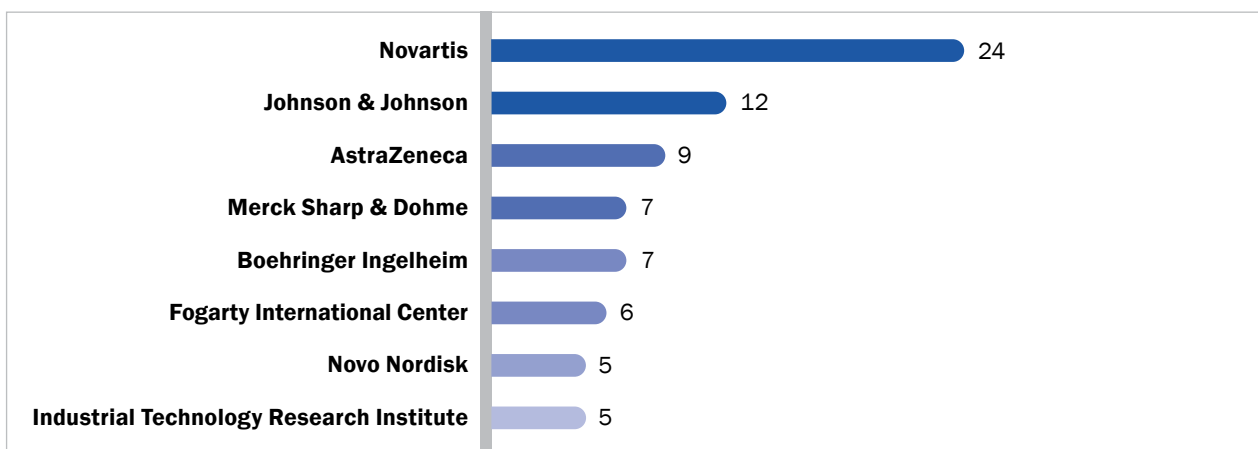


Figure 8: Top Sponsors that contributed to new sponsored research in 2022

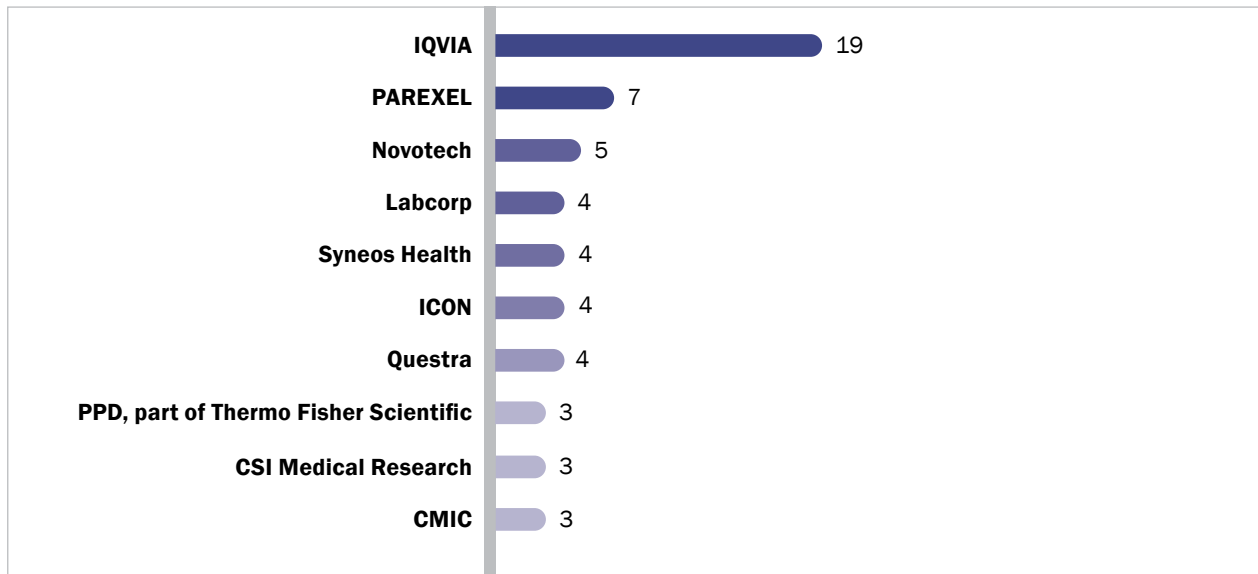


Figure 9: Top CROs that contributed to new sponsored research in 2022



New partnerships also pave the way to driving opportunities that optimise clinical trial delivery. In 2022, few key partnerships were formed to further enhance clinical trial activities, some in addition were also focused on elevating the capabilities of study team members, through training programs.

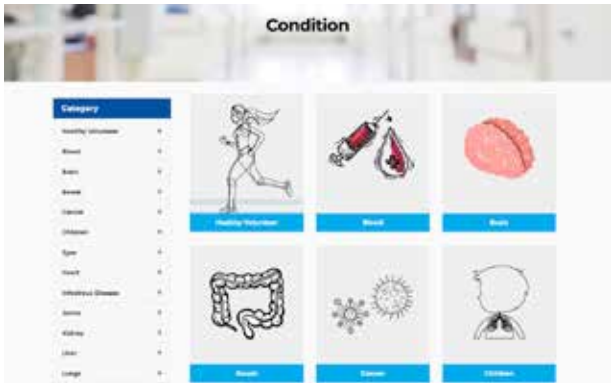
Table 2: New partnerships inked in 2022

NEW PARTNERSHIPS	PURPOSE
Drug for Neglected Diseases initiative (DNDi)	Research focused on re-purposing drug compounds for dengue treatment
National Center for Global Health and Medicine, Japan	Collaboration through ARO Alliance for ASEAN and East Asia (ARISE)
Princess Margaret Cancer Centre, Canada	Cooperation in clinical, academic and research opportunities, especially on early phase research
Syneos Health	Forming the 1st Catalyst Site Network in APAC under Syneos Health's Catalyst program
Novartis	Enhancing Sarawak General Hospital as a center of excellence for First-in-Human trials

Engaging through 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. The campaign is conducted through physical roadshows as well as social media engagement, to deliver better outreach to the public on facts on clinical trial. With 35,000 followers across all its social media platforms and over 34 million in impressions gathered just in 2022, 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 2022, the platform had over 160 people registering their interest, spanning over 30 disease conditions.



Our People

At the core of being self-sustainable and self-sufficient, CRM has grown stronger with stable and prudent finance management. The people of CRM is our greatest assets to this organization, and the success of the company relies on them. With this in mind, in 2022, CRM tabled several incentives for the people of CRM and was approved by the Board of Directors. Among this include:

Conversion of fixed-term contract to regular staff

Year-end pay-out

Monthly critical allowance

The incentives were successfully implemented, thus enhancing attraction to potential new joiners, improve staff retention and productivity, and boosts morale and motivation. The 2021 vs 2022 attrition rate fell from 16.8% to 12.8%.

Sensitive to Community Around Us

HUMANITY is also to be sensitive to our environment and community around us. The flash floods that occurred in December 2022 has also affected some of CRM's Study Coordinators in the East Coast. CRM lend our support to our affected team members and provided flexible working arrangement at home.

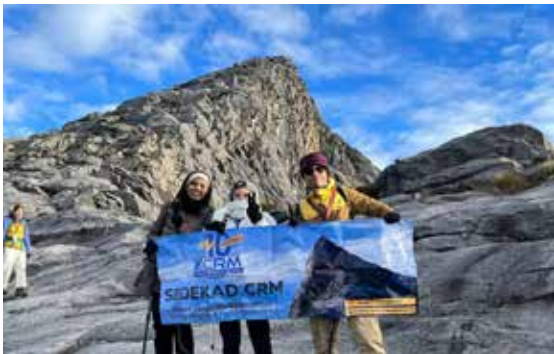


Additionally, CRM exercised its Corporate Social Responsibility (CSR) during the recent flood that affected several states in the country which resulted in losses and damages of assets. A donation of RM 10,000 was made to IMARET (IMAM Response & Relief Team), a humanitarian disaster response organization that deploys aid in flood-affected areas. Others CSR activities include donation to Pertubuhan Amal Kebajikan Agama dan Masyarakat (PERAKAM) as well as Persatuan Kebajikan Ceriajaya Kuala Lumpur dan Selangor to support the SMA (Spinal Muscular Atrophy) community.

Work-life balance

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CRM emphasizes a work-life balance for its employees. Several activities carried out throughout the year including the Mount Kinabalu climb which saw participation of 16 of CRM employees hiking up the highest mountain in Southeast Asia. The CRM Sports and Recreational Club (SRC) also organized several other activities including Movie Night, CRM Gala Dinner and the CRM National Conference.



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 2022 was no exception with some achieving double digit percentage growth. The cherry of the success in 2022 is in breaking the **RM1 billion** mark of gross national income brought in through clinical research contract value since the conception of CRM in 2012. 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.

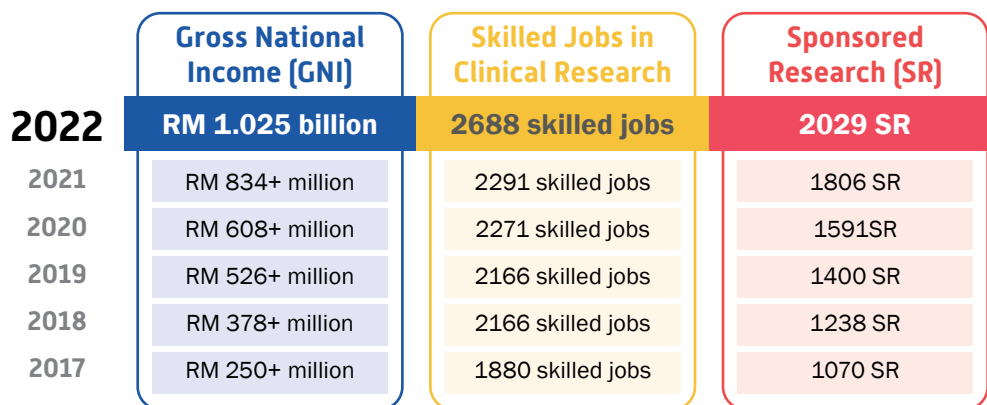


Figure 10: KPI Scorecard from 2017 – 2022

Clinical Trial Sites

In retrospect, the majority of sponsored research are conducted in MOH trial sites. However, it is also encouraging to note that the share of sponsored research conducted in Ministry of Higher Education (MoHE) institutions and the private sectors are also growing in tandem over the years, owing to the fact that these sectors have built on their capacities and experience in sponsored research and have flourish in this field.

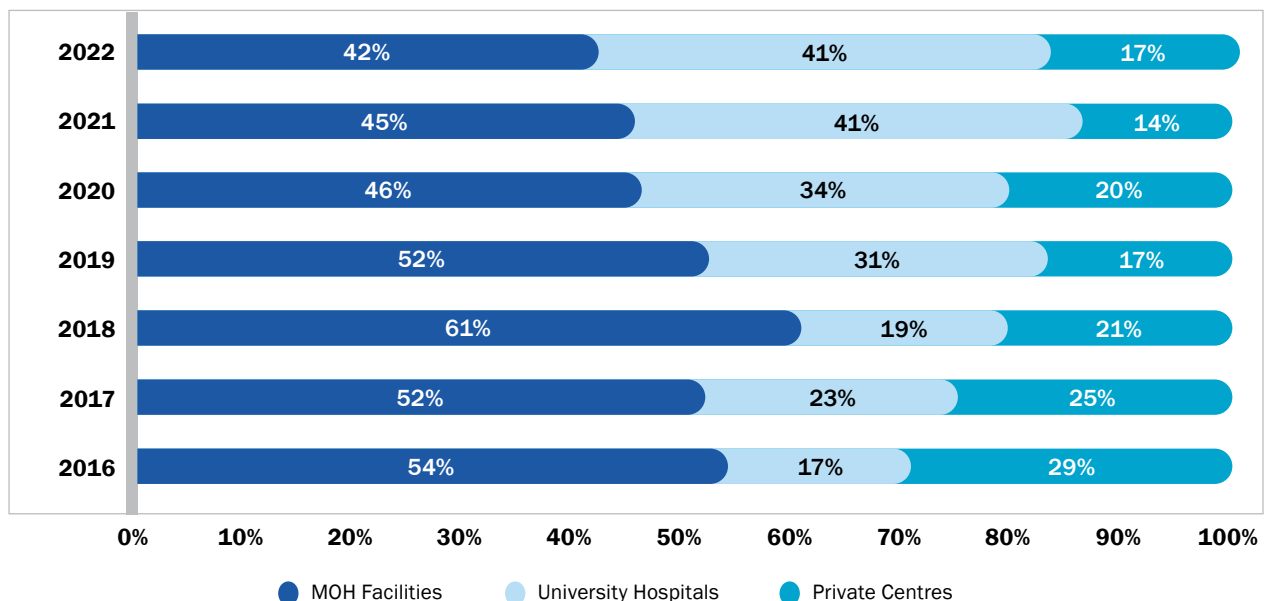


Figure 11: Distribution of Sponsored Research between different site sectors (2016 – 2022)

STABILITY

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CLINICAL RESEARCH MALAYSIA

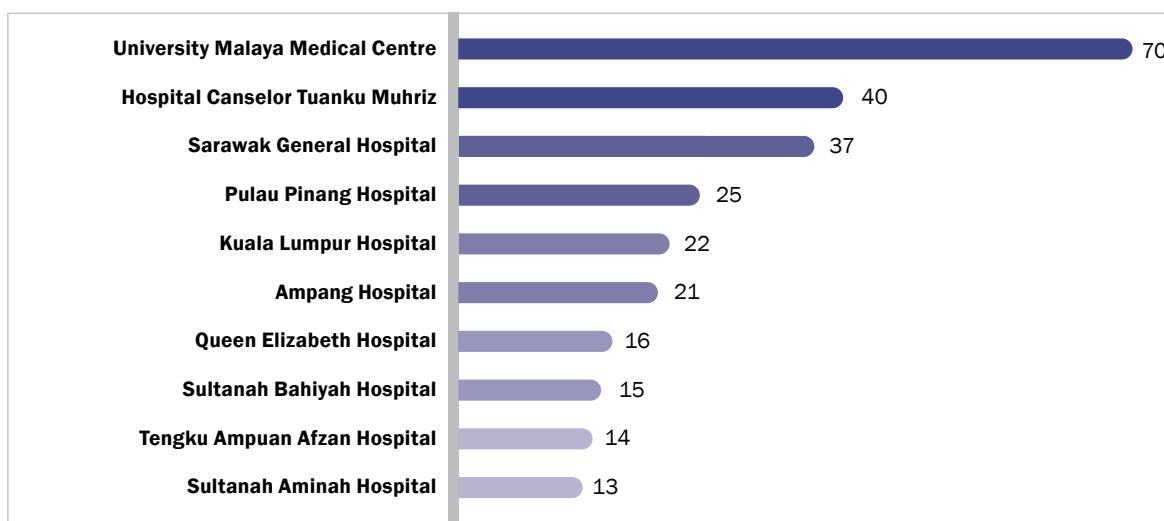


Figure 12: Top Trial Sites based on new sponsored research in 2022

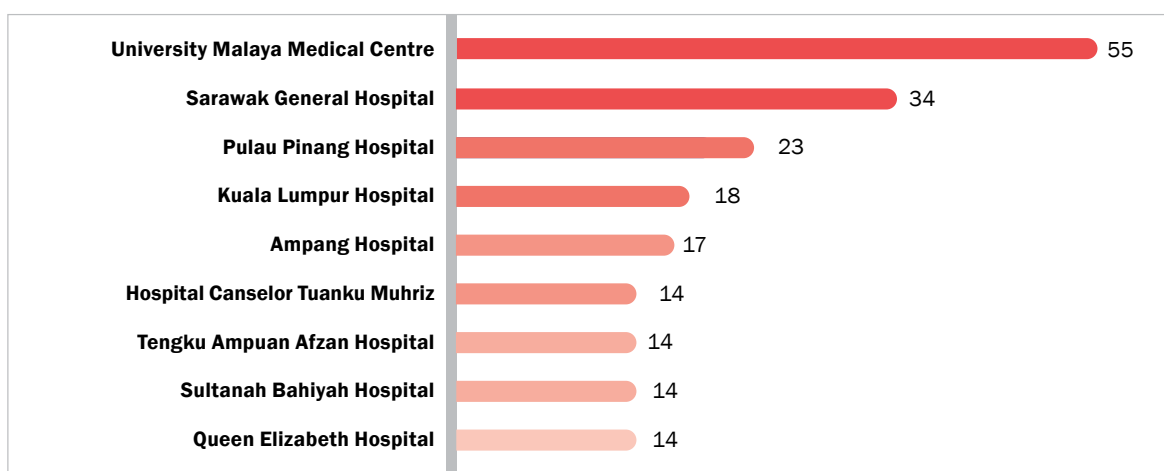


Figure 13: Top Trial Sites based on new interventional sponsored research in 2022

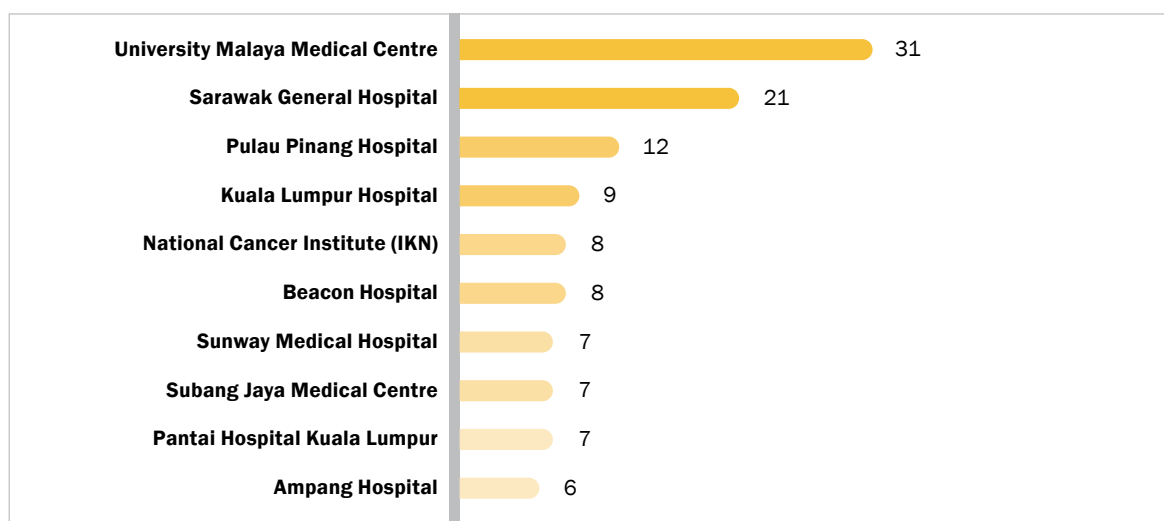


Figure 14: Top trial sites based on new oncology/ hemato-oncology studies in 2022

Site Recruitment Achievement

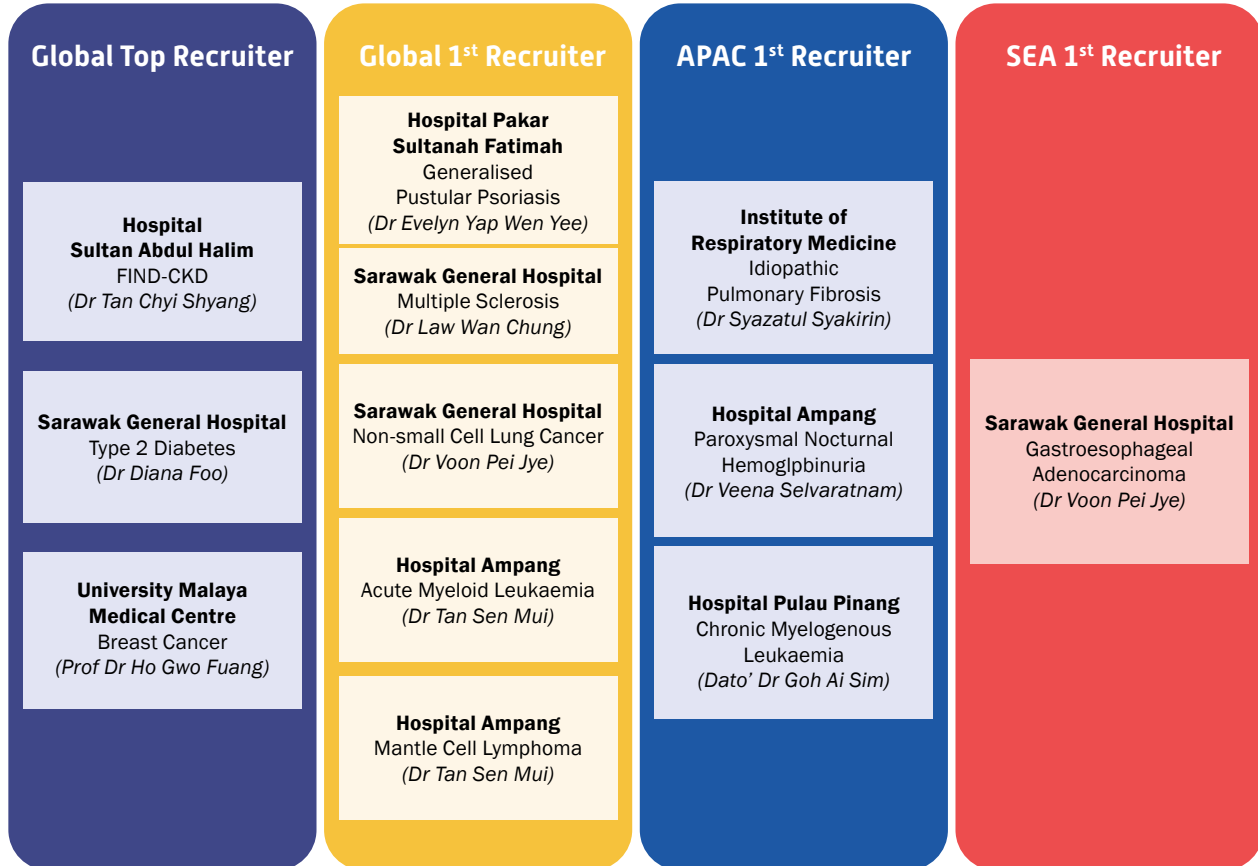


Figure 15: Site recruitment achievement in global trials, 2022

To date, there have been over 220 study sites in Malaysia with experience in the conduct of sponsored research. Many of these sites supported by CRM Study Coordinators have performed well in study recruitments and this have been acknowledged by global sponsors and CROs. The hard work and commitment by Investigators and study team in these sites have resulted in their study achieving Global Top and First Recruiters. Sites such as Sarawak General Hospital, Penang Hospital, Ampang Hospital and the Institute of Respiratory Medicine have also earned distinction as first recruiter in the region. This excellent delivery has put Malaysia third in Southeast Asia in number of sponsored research. This is an element of **STABILITY** that CRM has consistently and reliably delivered to meet the recruitment target and expectations.

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 2022 is no different. This further establishes CRM's business as efficient and self-sufficient in generating its own capital and operational expenditure.

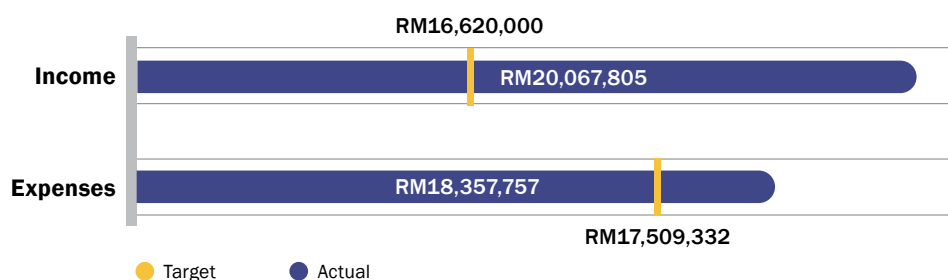


Figure 16: Clinical Research Malaysia Finance Performance in 2022

STABILITY

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CLINICAL RESEARCH MALAYSIA

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 20,459 invoice to sponsors and CROs with a total amount of close to RM350 million.

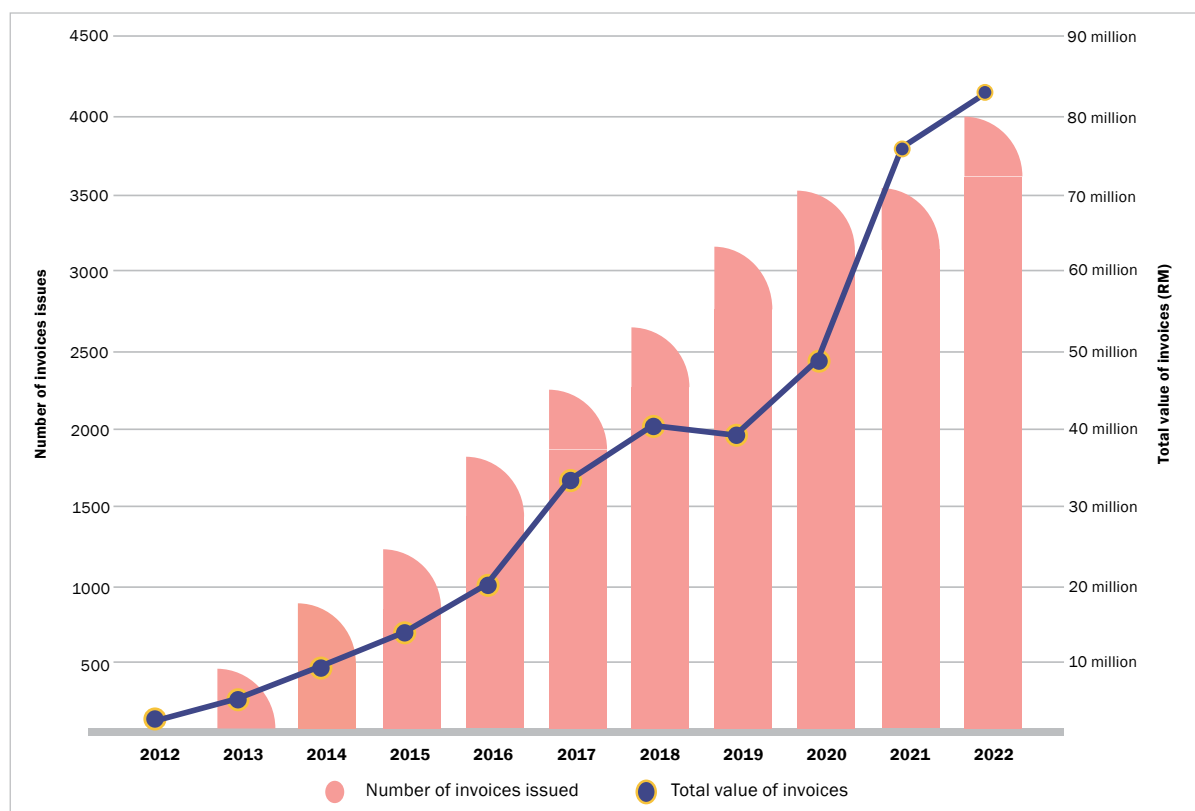


Figure 17: Invoices Issued by CRM between 2012 - 2022

Investing in Human Capital Development

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.

Internal	External
Training to Improve Performance of SC (TIPS): Train the Trainer	American Society of Clinical Oncology (ASCO)
TIPS for Study Coordinators	European Society of Medical Oncology (ESMO)
Patient Recruitment and Retention Workshop	DIA-CoRE Singapore
Preparation for Regulatory Inspection Workshop	ESMO Asia Congress 2022
Protocol Compliance Workshop	
GCP Refresher Workshop	

Table 3: Training and development programs in 2022

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 12% 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 2022

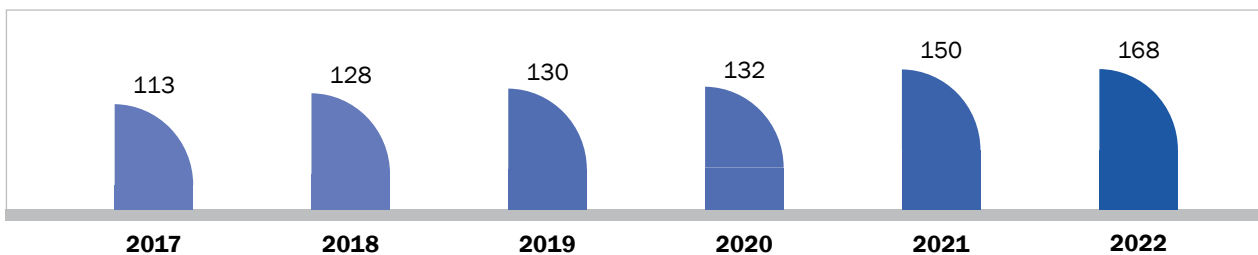


Figure 19: Growth of number of CRM Study Coordinators from 2017 – 2022

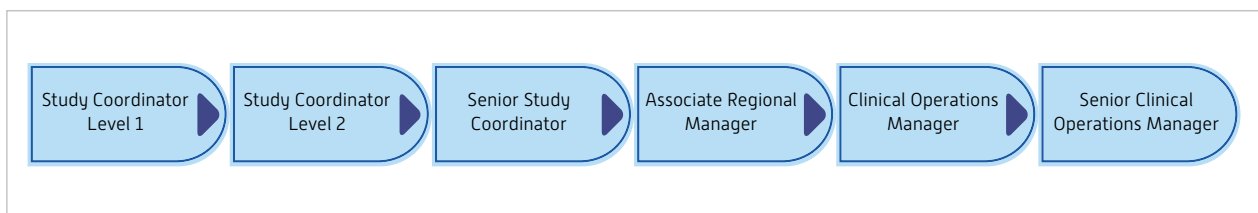


Figure 20: CRM study coordinator career development

As part of CRM's Phase 1 Realization Project 2.0 to create a research team that is capable in conducting early phase clinical research, CRM have engaged with several globally renowned early phase institutions to explore opportunities to send study teams for hands-on training in phase 1 trials. Among the institutions CRM have engaged with include Princess Margaret Cancer Centre, The Christie NHS UK, NUHS Singapore, Northwestern Memorial Hospital US, National Cancer Center Japan and the University of Cambridge.

On 7th December 2022, CRM signed a Memorandum of Understanding with Princess Margaret Cancer Centre (PMCC), Toronto, that spells cooperation in the areas of clinical, academic and research opportunities for both organizations. This MoU will thus enables CRM to send two (2) of its SC for training placement at PMCC in 2023 to provide them with the needed exposure and experience in managing first-in-human trials.





SUSTAINABILITY

Creating a Conducive and Sustainable Environment

CRM recognizes the importance of **SUSTAINABILITY**. This 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 of its people. Moving into 2023, below are some of the developments and progress CRM have made with its people in mind:

- CRM defined working hours of its employees, with overtime allowance, in line with the changes in Malaysia's Employment Act 1955.
- Revision of maternity & paternity leave
- Revision of the CRM Employee Code of Conduct which includes:
 - New policy and guidelines on harassment & discrimination
 - Improved clauses on whistleblowing

As a globally trusted research management organization, CRM is committed in creating a conducive and sustainable working environment through:

Adhering to the Quality Management System (ISO 9001:2015) and the Anti-Bribery Management System (ISO 37001:2016)

Complying to CRM's Core Values & Code of Conduct

Creating environmentally sustainable business (eg. archiving & study material destruction)

Ensuring practices within the company adheres to the personal data protection and confidentiality

SUSTAINABILITY

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CLINICAL RESEARCH MALAYSIA

At the helm of **SUSTAINABILITY** is our ability to showcase the organization's efficiency in delivering clinical trials through impactful activities such as the CRM Trial Connect conference, followed by the Appreciation Dinner to celebrate the various successes achieved by the people of CRM.



What's next

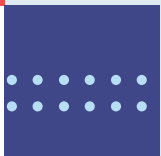
A huge part of the **SUSTAINABILITY** element is our vision in the next four years, which is to conduct a total of 1,000 new sponsored research by 2026, create 2,500 skills jobs in clinical research, achieve 500 new sponsored research in MoH trial sites, produce a cumulative income of RM100 million, grow the organization's business with an investment totaling to RM95 million and generate Gross National Income through a cumulative value of RM 540 million in clinical trial contract agreements. This vision is to be driven through operational excellence throughout all departments within the organization, in line with the company's four (4) key strategies, which are:



Figure 21: CRM's key strategies



Figure 22: CRM's Vision 2023-2026



ADVERT

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CLINICAL RESEARCH MALAYSIA

CLINICAL TRIAL ADVERTISEMENT SERVICES



PLATFORM

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

contact: bd@clinicalresearch.my

STUDY MATERIAL 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

contact: komala@clinicalresearch.my



ACKNOWLEDGEMENTS

Editorial Board

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