PhAMA
Pharmaceutical Association of Malaysia

UNLOCKING MALAYSIA'S POTENTIAL IN CLINICAL TRIALS

A PERSPECTIVE FROM MULTINATIONAL PHARMACEUTICAL COMPANIES

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The views and opinions expressed herein are those of the authors and do not necessarily reflect the official policy or position of any organization.

TRIBUTE TO DR. BALRAJ SETHI, COUNTRY MEDICAL DIRECTOR, NOVARTIS MALAYSIA

On 24 September 2024, Dr Balraj Sethi was tragically involved in an accident while on a pilgrimage with his family in India. At time of publication, Dr Balraj has yet to be found. Our hearts are with his family, and we remain hopeful for his safe return. On behalf of the Malaysian healthcare sector, PhAMA acknowledges the immense value and impact he provided to the community in our country.

Throughout his career, Dr. Balraj Sethi has been an unwavering champion of clinical research at Novartis Malaysia, embodying a true spirit of dedication and excellence.

Guided by strong empathy and humanistic instinct, he helped shape the landscape of clinical research by emphasizing on patient safety and ensuring that Malaysians receive the highest standards of care in trials by adhering to the strictest ethical guidelines.

Balraj's passion for 'leaving no patient behind' enhanced trust between researchers and participants, further cementing Malaysia's position as a global leader in clinical research.

This factbook bears testament to his leadership, unwavering passion, and relentless pursuit of excellence while prioritizing human life.

As we turn its pages, we are reminded of the profound impact that one individual can have on an entire industry.

We hope it will serve as an inspiration to all those who wish to follow in his footsteps.

ACKNOWLEDGEMENTS

We extend our gratitude to everyone who has contributed to the creation of this factbook in one way or another. Their unwavering support and expertise have been invaluable to support the articulation of the key elements. Notable contributions as follows:

1. Data, case studies and evidence support from all participating multinational pharmaceutical companies

2. Patients and healthcare providers in sharing their experiences and feedback about clinical trials in Malaysia

3. Senior multinational pharmaceutical company executives for sharing their time and insights during content working sessions:

   CO-CHAIRS OF THE PhAMA CLINICAL RESEARCH COMMITTEE

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   Irvine Pang, Clinical Operations Manager – CVD SG, MY & TH, Novo Nordisk

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6. **Audrey Ooi**, Head of Business Development, Clinical Research Malaysia

7. **Asha Thanabalan**, Senior Manager, Business Relations & Corporate Communications, Clinical Research Malaysia

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MESSAGE FROM THE MINISTER OF HEALTH

As Malaysia advances towards becoming a high-income nation, our healthcare sector is undergoing a transformation. Biopharmaceutical innovation and life sciences are not just economic opportunities; they are essential pillars of our national progress. Clinical research is at the heart of this journey, enabling us to deliver world-class healthcare while driving scientific and economic growth.

Today, Malaysia is not just participating in the global clinical research landscape, but also shaping its future. I am pleased to share that Malaysia is now ranked among the top 30 globally and as the leader in Southeast Asia for global clinical trial readiness, as highlighted in the recent "Rethinking Clinical Trial Country Prioritization 2024" report.

This achievement is the result of years of strategic development. Since the establishment of Clinical Research Malaysia (CRM) in 2012, the Ministry of Health has worked tirelessly to build a clinical research ecosystem that is efficient, globally competitive, and patient-centric. With a diverse patient population, a robust regulatory framework, and a highly skilled medical workforce, Malaysia has emerged as an ideal destination for global clinical trials.

> "Clinical research is about more than just rankings and efficiency—it is about saving lives"

A major milestone has been the dramatic reduction in clinical trial start-up time — from 350 days in 2012 to just three months today. This reflects our commitment to efficiency, regulatory excellence, and adherence to global best practices.

However, clinical research is about more than just rankings and efficiency—it is about saving lives. Behind every trial is a patient—a mother, a father, a child—who is given renewed hope through access to life-saving and life-changing treatments. By advancing clinical research, we are not only strengthening our healthcare system but also delivering real impact to the lives of our people.

Multinational pharmaceutical companies have been crucial enablers of this progress, investing in Malaysia's research ecosystem and supporting patient access to novel therapies. Their continued collaboration will be instrumental in propelling Malaysia as a regional hub for clinical research and innovation.

This factbook comes at a pivotal moment as Malaysia activates its healthcare reform agenda. But we cannot do this alone. We call upon industry leaders, researchers, and policymakers to join us in shaping the next chapter of medical innovation. Together, we can position Malaysia as a global leader in life sciences, ensuring better healthcare outcomes for generations to come. Thank you.

DR. DZULKEFLY AHMAD
MINISTER OF HEALTH

MESSAGE FROM THE PRESIDENT OF PHAMA

Clinical research plays a critical part in drug discovery and medical advancements. In my last two decades holding different roles in the pharmaceutical industry, I can bear witness to the impact of clinical research on the lives of patients and their families.

What was even more inspiring was the dedication and commitment of trial investigator—the doctors, study coordinators, and their teams—who put in so much hard and heart work into a clinical trial with the objective of finding new cures for their patients. This willingness to go the extra mile is among the key factors for industry players in the selection of investigators and trial sites.

This is what PhAMA hopes to capture beyond the facts and figures in this Factbook. While clinical research is technically an investment today for a better health system tomorrow, we acknowledge and recognize the resilience and sacrifice of investigators and patients who participate in trials in one way or another. That, surely, goes beyond dollars and cents.

While Malaysia has ranked 1st in Southeast Asia recently for country readiness in global clinical trials, there are still opportunities for improvement. Specifically, within areas of infrastructure, skilled and experienced workforce, operational hiccups, and others, are some hurdles that we need to overcome to keep Malaysia at pole position of the clinical research sector in the region.

> "We acknowledge and recognize the resilience and sacrifice of investigators and patients who participate in trials"

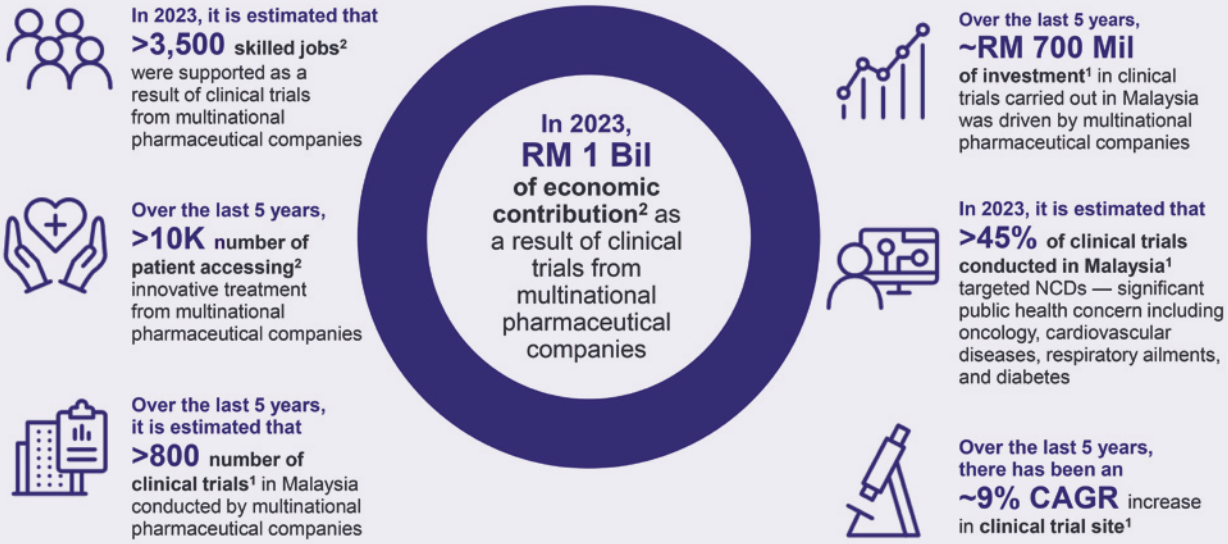
By working together, we believe that these challenges can be overcome. With the government's commitment to enhance clinical trial infrastructure, strengthen regulatory frameworks and invest in capability building for researchers, the clinical research sector looks promising. This will provide the confidence for more multinational pharmaceutical companies to invest into conducting global trials in Malaysia in time to come.

To boost these collective efforts, the PhAMA Clinical Research Committee has been playing an active role in the sector by being part of the JPKK (Jawatankuasa Penyelidikan Klinikal Kebangsaan)/National Committee for Clinical Research, and supporting Clinical Research Malaysia (CRM) in making the country a regional hub for clinical research.

On behalf of the Board of Directors, I would like to congratulate the PhAMA Clinical Research Committee and the PhAMA Secretariat for making this Clinical Research Factbook a reality. May our shared goals bring new hope and a better quality of life for those who matter the most – the patients. Thank you.

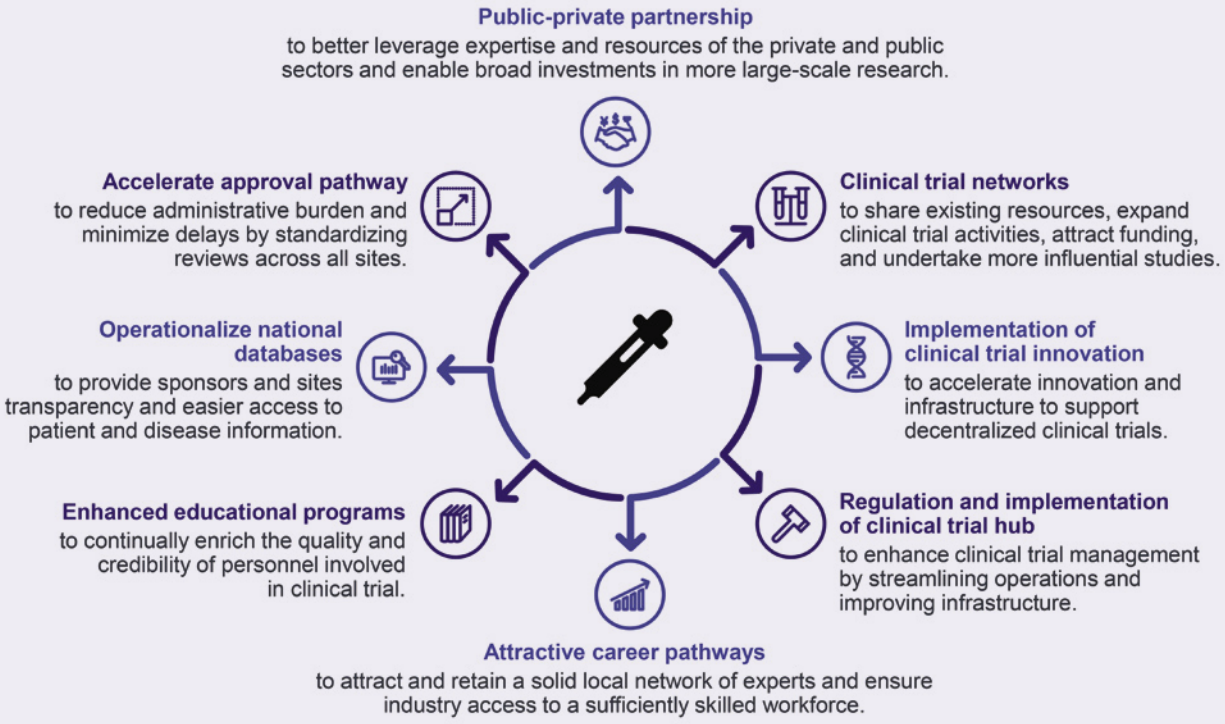
MS. KAM AI TENG
PRESIDENT
PHARMACEUTICAL ASSOCIATION OF MALAYSIA

Economic and non-economic contributions of clinical trials in Malaysia driven by multinational pharmaceutical companies



Source: 1 Clinical Research Malaysia Report | 2 IQVIA Analysis

Paving the way for clinical trial excellence



INTRODUCTION

Clinical trials play a crucial role in healthcare by helping us determine whether new treatments are safe and effective for people. These studies are essential for developing new medications, medical devices, and treatment methods. They are conducted to test new treatments, improve existing ones, and advance medical knowledge. Clinical trials ensure that new treatments are safe for humans, assess their effectiveness, and compare them with existing treatments to find the best options.

The process of clinical trials starts with pre-clinical research, which involves laboratory and animal studies to gather initial data. This is followed by Phase 1 trials, which include First-in-Human (FIH) studies, a critical step where a new drug or treatment, after rigorous lab and animal testing, is given to a small group of humans for the first time to determine a safe dose range and assess safety and tolerability. Phase 2 trials involve a larger group of patients to evaluate effectiveness and side effects. Phase 3 trials are large-scale tests to confirm effectiveness, monitor side effects, and compare the new treatment with standard treatments. Finally, Phase 4 trials are post-marketing studies that gather additional information on risks, benefits, and optimal use.

Clinical trials are governed by strict regulations to protect participants. Regulatory authorities, such as the Food and Drug Administration in the U.S. or the National Pharmaceutical Regulatory Agency in Malaysia, oversee the approval and monitoring of clinical trials. Ethics committees, which are independent groups, review and approve trial protocols to ensure ethical standards are met. Participants must be fully informed about the trial and voluntarily agree to participate, a process known as informed consent. Continuous safety monitoring is conducted throughout the trial to ensure the safety of participants.

In Malaysia, clinical trials are conducted under the oversight of NPRA and adhere to international standards. The process involves obtaining approval from NPRA to ensure the trial meets regulatory requirements, undergoing ethics committee review and approval to ensure the trial is ethically sound, besides ensuring the safety and rights of participants are protected.

EXECUTIVE SUMMARY

Clinical trials are pivotal to a country's health and economic development. They not only advance medical knowledge and improve patient care but also attract significant investments, create jobs, and enhance the nation's global standing in the healthcare sector. By fostering innovation and ensuring the availability of cutting-edge treatments, clinical trials contribute to a healthier population and a more robust economy.

Since 2012, Malaysia's clinical trial sector has experienced a remarkable transformation. The establishment of Clinical Research Malaysia (CRM) marked the beginning of a new era, with the country rapidly becoming a preferred destination for global industry-sponsored studies. The sector's growth has been driven by Malaysia's strong healthcare infrastructure, diverse population, and competitive trial costs. By In 2023, Malaysia had achieved a record-breaking 276 newly sponsored clinical research studies, as well as over 2,305 clinical trials conducted since 2012, underscoring its rising prominence in the global clinical research landscape.

The economic impact of this growth has been substantial. As of May 2024, sponsored clinical research has contributed over RM1.538 billion in cumulative gross national income since 2012, creating numerous job opportunities and fostering skills development within the local workforce. The Malaysian government's commitment to making the country a regional hub for clinical research, supported by favorable policies and a conducive environment, has further solidified Malaysia's position as a key player in the industry. This journey reflects not only the sector's resilience and potential but also Malaysia's dedication to advancing healthcare and economic prosperity.

Malaysia's clinical trial sector has been instrumental in several notable success stories and ground-breaking treatments, such as:

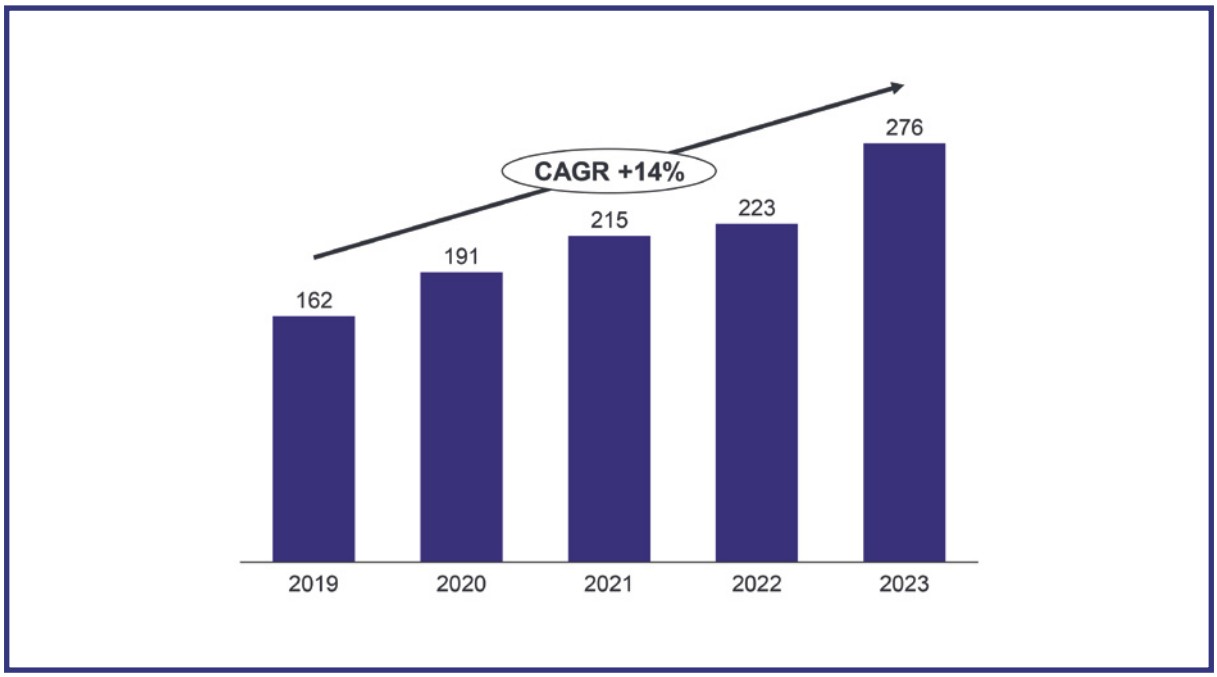
First-in-Human Trials

Malaysia's clinical trials sector has achieved significant milestones, establishing itself as a key player in early-phase research, with Sarawak General Hospital earning international acclaim for a global First-in-Human (FIH) study (the first time a new drug or treatment is tested in humans). Additionally, Ampang Hospital was established in 2006 and accredited as a Phase 1 unit in 2022, launching its first First-in-Patient study (a trial involving the first patient to receive a new treatment) in November 2023. These trials will helped position Malaysia as a key player in early-phase clinical research, attracting global biopharmaceutical companies to conduct their trials in the country. Some notable recent examples have included Roche being the first PhAMA member to bring in first FIH trials in Malaysia announcing three FIH trials alone this year, with one in immunology and two in oncology in 2024, as well as AstraZeneca announcing a FIH study for solid tumors, which was the first FIH trial in Malaysia to use a biological product. MSD has designated Malaysia for the Phase 1b study in 2024, marking a promising initial step toward the potential allocation of FIH trials in the region, while Johnson & Johnson has been conducting phase 1b trials in Malaysia since 2017. These First-in-Human trials are conducted with very strict protocols and with continuous safety monitoring throughout the trial, ensuring the safety of participants while enabling patients to gain access to life-changing treatments. By advancing clinical research, we are not only strengthening our healthcare system but also uplifting Malaysia as a regional hub for clinical research and giving patients renewed hope through access to novel therapies.

Partnerships

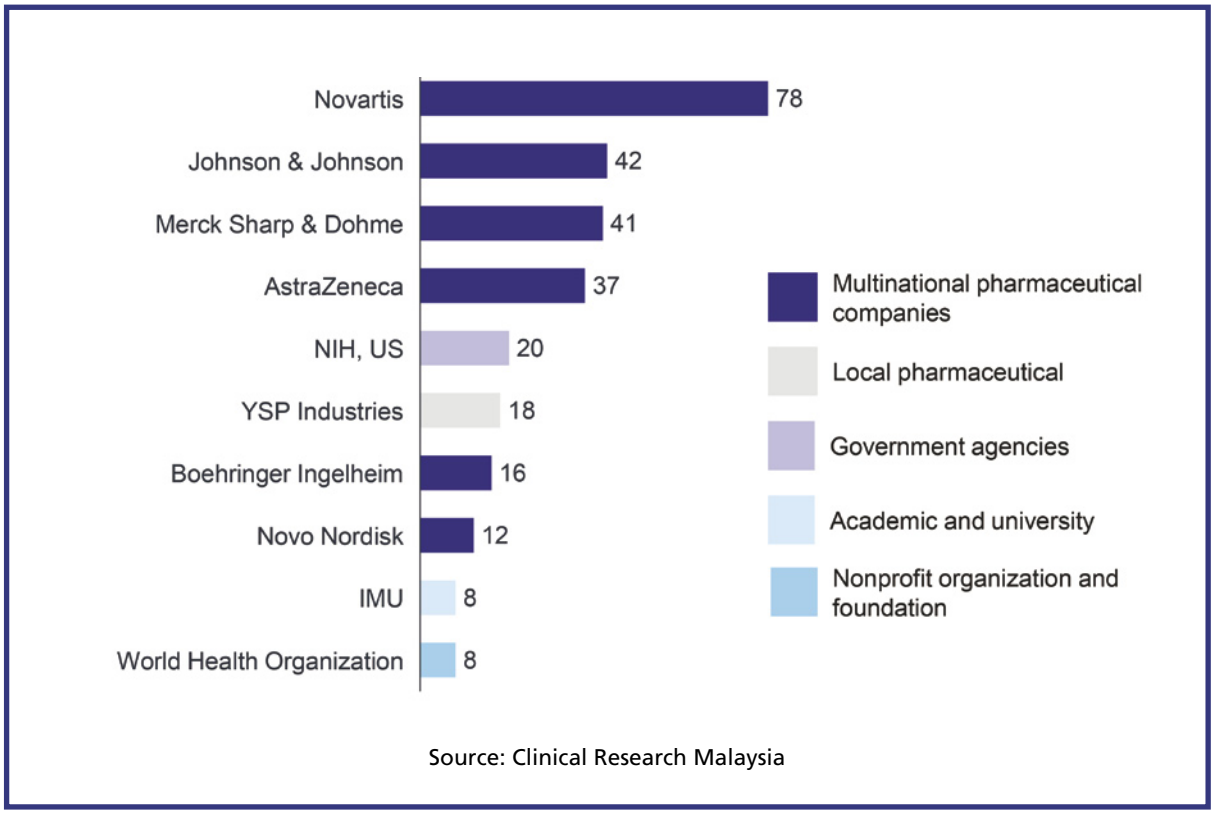
Malaysia's positioning as a clinical research hub has also spurred on partnerships with other institutions. Recently, Clinical Research Malaysia (CRM) and The Chinese University of Hong Kong (CUHK) entered a landmark collaboration in April 2024, with this Memorandum of Understanding (MoU) underscoring joint efforts in the areas of clinical, academic, and research opportunities at both organizations as it further consolidates the efforts led to upskilling the researchers as well as in driving knowledge exchange in clinical research. Both CRM and CUHK are dedicated to promoting and facilitating collaboration, innovation, and clinical research between both nations. Other MoUs that CRM has inked with global institutions include with National University Hospital Singapore, Singapore Clinical Research Institute, Princess Margaret Cancer Centre and the National Cancer Centre Japan; to collaborate in areas of human resource capability development and clinical research collaboration.

FIGURE 1 Number of sponsored research in Malaysia (2019–2023)



Source: Clinical Research Malaysia

FIGURE 2 Top 10 Sponsors in New Sponsored Research (2019-2023)



Source: Clinical Research Malaysia

Source: Clinical Research Malaysia

CHAPTER 1:
The role of multinational pharmaceutical companies in advancing clinical trials in Malaysia

Malaysia's clinical trials sector has been progressing significantly in the last 10 years with the recent breakthroughs such as entering early-phase research. These accomplishments underscore Malaysia's efforts and desire to enter a globally competitive research space which has long been dominated by other Asia Pacific countries.

These milestones were not achieved overnight; Malaysia's clinical trial sector has undergone a remarkable transformation, which could not have been achieved without the partnership of multinational pharmaceutical companies, which have contributed substantially to the economic and non- economic impact of the clinical trials sector in Malaysia, as well as the overall healthcare ecosystem.

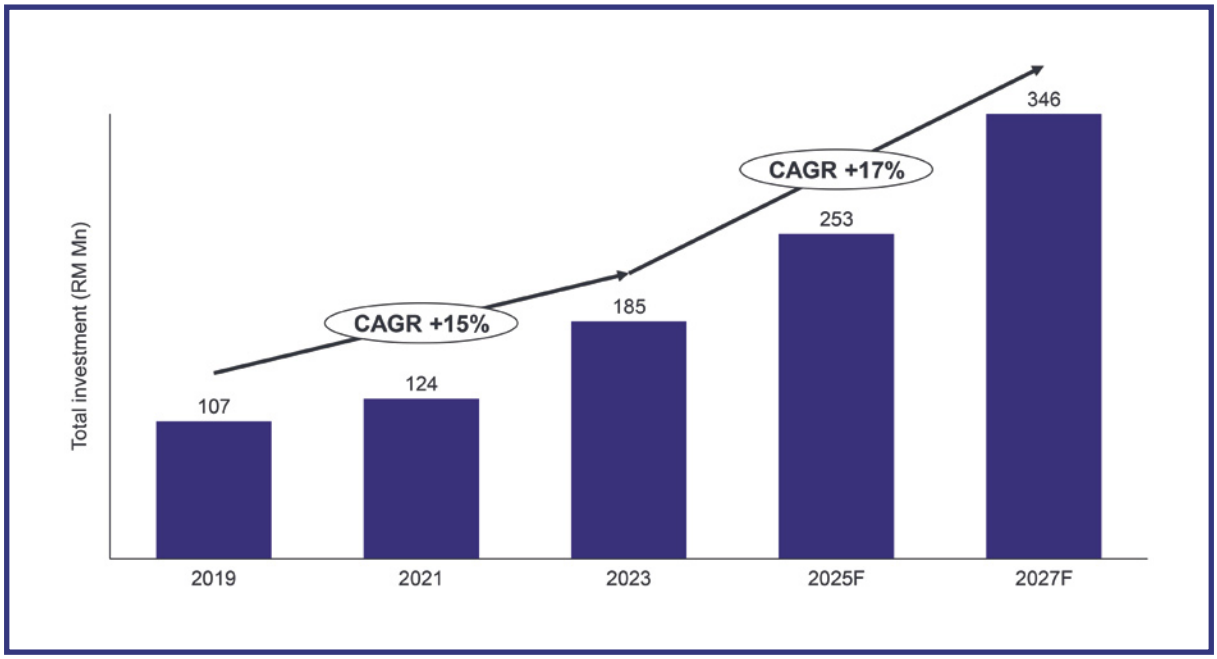
Over the years, multinational pharmaceutical companies have continuously invested in clinical trials globally, with Malaysia being one of the destinations for certain therapeutic areas. These global entities bring extensive resources, advanced technology, innovative approaches, and the latest scientific knowledge to the process, inevitably enhancing the development of new treatments and therapies in the countries they are present in. Multinational pharmaceutical companies also enable access to leading global experts through forums and conferences such as the Healthcare Asia Forum, the Word Cancer Congress, and the Neurology Summit which were held in Kuala Lumpur. Multinational pharmaceutical companies also collaborate with the government and other key stakeholders to elevate Malaysia as a competitive hub for high-quality clinical trials, driving global investment and strengthening the local healthcare infrastructure, enhancing Malaysia's visibility and ability to compete globally.

Multinational pharmaceutical companies have significantly contributed to the clinical trial landscape in Malaysia, accounting for approximately 80-90% of the total investment in this sector. This substantial investment signals the active participation between multinational pharmaceutical companies and Malaysian hospitals in conducting clinical trials across various therapeutic areas, including oncology, cardiology, neurology, infectious diseases, endocrinology, and other high-burden diseases. The broad swathe of therapeutic areas covered by these trials reflect the strong presence and leadership of multinational pharmaceutical companies as well as their continued investment confidence in Malaysia.

Figure 1 illustrates that Malaysia recorded its highest number of sponsored research studies since the founding of Clinical Research Malaysia, with 276 studies conducted. Of these, in 2023, 4568% were carried out in Ministry of Health (MOH) facilities. The number of sponsored research projects grew at a Compound Annual Growth Rate (CAGR) of 14% within 5 years.

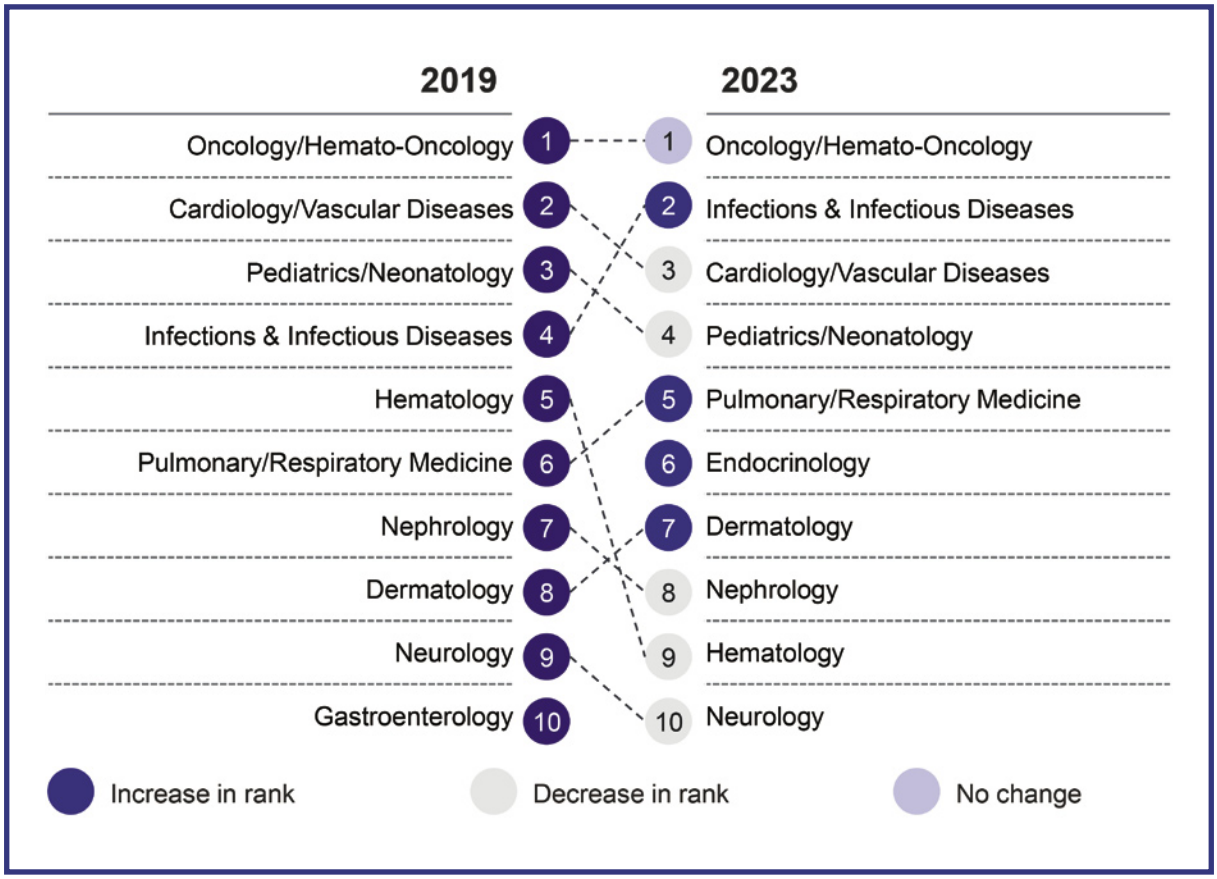
> "Our successful execution of First-in Human trials in Malaysia demonstrates our country's capability to deliver high quality, innovative research. With our dedicated investigators and efficient processes, we are poised to become a leading destination for global clinical trials"
>
> — **Sheikh Mohammad Norhafiz Abdul Aziz**
> Country Clinical Operations Lead, Roche

FIGURE 3 Total investment of multinational pharmaceutical companies in clinical trials (2019-2027F)



Source: IQVIA Analysis

FIGURE 4 Investment trends in clinical trials for top Therapeutic Areas (2019-2023)



Source: Clinical Research Malaysia

TABLE 1 First-in-human Trial Milestones in Malaysia

2017	Malaysian Phase I Clinical Trial Guidelines was launched
2017 - 2019	Three officers from NPRA sponsored by CRM to pursue postgraduate programme under CRM's Phase 1 Realization Project - people development initiative
2018	Establishment of Scientific Review Panel to provide expert opinion to MREC on FIH studies
2019	NPRA developed its Phase 1 Unit Inspection & Accreditation Programme to accredit FIH sites.
2020	CRM sponsorship of Dr Voon Pei Jye to undergo Phase 1 Fellowship at Princess Margaret Cancer Center
2021	First-in-Patient (FIP) haematology study was conducted in Sarawak General Hospital (SGH) and SGH was recognised as First Global Recruiter
2023	First FIP haematology study conducted in Ampang Hospital
2023	First FIH oncology study conducted in SGH
2024	SGH was selected by Roche as its site for FIH clinical trial under Rheumatology indication. SGH was recognized as First APAC Recruiter.
2024	SGH was selected by AstraZeneca to conduct its FIH study involving biologics for solid tumour
2024	Roche continues to expand its FIH clinical trials for Oncology indication at SGH in April 2024, followed by a second FIH Oncology trial awarded in July 2024.

Figure 2 highlights the leading entities in new sponsored research in 2019-2023, with multinational pharmaceutical companies emerging as the majority contributors. Growth of sponsored clinical research is also dependent on Malaysia's pharmaceutical companies' presence and efforts.

Building on this, Figure 3 highlights that multinational pharmaceutical companies increased their investments in Malaysia's clinical trial sector at a CAGR of 15% from 2019 to 2023. We project that this CAGR will accelerate to 17% from 2023, reaching RM 346 million by 2027. This projected growth is driven by the establishment of a more conducive environment for clinical trials in Malaysia, including enhanced infrastructure, adjusted regulatory frameworks, and increased government and private sector support. This growth is projected to surpass the global clinical trials market growth rate, which is expected to grow at CAGR 6.49% from 2024 to 2030 with continued investments from multinational pharmaceutical companies in Malaysia and continuous healthcare infrastructure advancements [1].

Figure 4 illustrates the trends in clinical trials in Malaysia which is consistent with global R&D trends, with significant activity in oncology, infectious diseases, and cardiovascular diseases. Multinational pharmaceutical companies with a R&D or clinical operations team in Malaysia can better advocate for clinical trial opportunities in Malaysia. The country's diverse genetic makeup offers a unique and varied patient pool, crucial for in-depth clinical studies and particularly advantageous for personalized medicine trials. Additionally, cancer has surged to become the fourth most common cause of death in Malaysia, underscoring the need for increased oncological research [2]. Furthermore, Malaysia's tropical climate makes it an ideal hotspot for clinical trials targeting tropical diseases, attracting global attention and research investment. These factors collectively position Malaysia as a potential hub for diverse and impactful clinical trial initiatives.

The investment size or "ticket" for clinical trials varies significantly across therapeutic areas, influenced by factors such as disease complexity, regulatory requirements, development phase, and the budget of trial sponsor. Oncology trials are one of the most expensive due to their intricate protocols, intensive patient monitoring, and the high costs of developing targeted therapies. Infectious disease trials, such as those for vaccines, can also be expensive due to large phase III trials and manufacturing considerations, although antiviral trials might cost less due to shorter durations and clearer endpoints. Costs are further influenced by the trial phase, with early-stage trials generally costing less than more extensive late-stage trials. Reflecting these dynamics, the investment "ticket" size by multinational pharmaceutical companies increased by 10% from 2019, reaching RM 2.1 million in 2023. The increasing costs of clinical trials makes Malaysia an attractive destination in balancing between costs and quality as Malaysia offers a comparatively cost-efficient option for conducting clinical trials.

The economic impact of clinical trials is significant, consisting of direct, indirect, and induced contribution. Direct impact stems from the expenditures of multinational pharmaceutical companies sponsoring trials, which are paid to hospitals, healthcare institutions, and local Clinical Research Organizations (CROs). Indirect impact comes from the secondary economic effect, including savings on healthcare costs related to healthcare burden and tax paid by related companies. Induced impact occurs when employees and businesses spend their earnings in the local economy, stimulating further economic activity.

Beyond economics, the non-economic benefits of clinical trials, though harder to quantify, are just as vital. These include improved patient access to cutting-edge treatments, enhanced medical knowledge, and better healthcare outcomes. From a health system perspective, the value-added lies in boosting healthcare quality, fostering innovation, and aligning with global health research trends.

Given the substantial economic impact that is derived from clinical trials, promoting a supportive environment for clinical trials is not just a priority for the pharmaceutical industry, but a key element of a well-rounded healthcare system. Future research should explore the long-term benefits of clinical trial investments on both public health outcomes and economic growth.

"It is our joint commitment to bring medical advances and hope to patients. We will continue to find the answers in clinical trials, which may lead to new possibilities."

— Irvine Pang
Clinical Operations Manager – CVD SG, MY & TH, Novo Nordisk

1.1 Economic contributions

FIGURE 5 Economic contribution from clinical trials in 2023

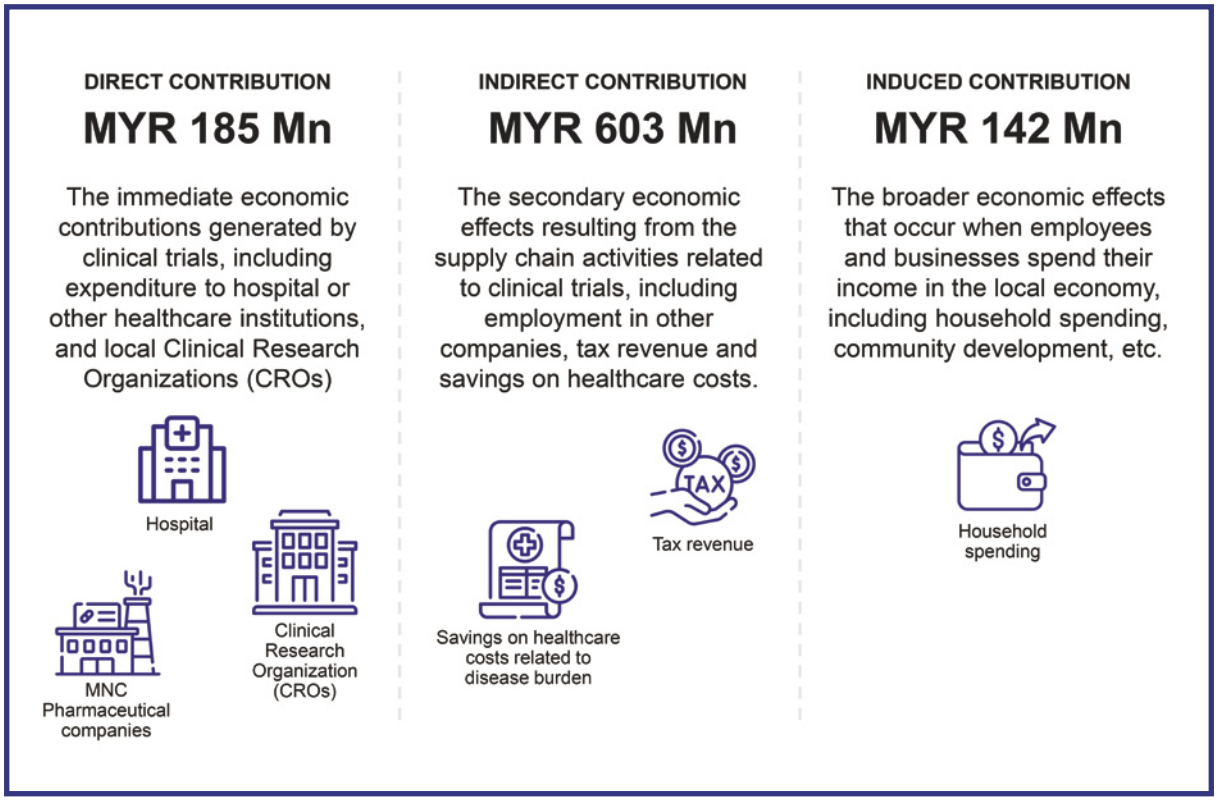


Figure 5 above illustrates that clinical trials have a significant economic impact on a country, encompassing direct, indirect, and induced effects. To quantify the indirect contribution, the health economic outcomes of clinical trials are assessed, and a monetary value is assigned to each DALY (Disability-Adjusted Life Year) averted, using GDP per capita as a reference point. Over the past five years, it is estimated that more than 10,000 patients have benefited from access to innovative treatments through clinical trials conducted by multinational pharmaceutical companies. These trials, numbering over 800, have been instrumental in addressing major public health concerns in Malaysia, with more than 45% focusing on critical areas such as oncology, cardiovascular diseases, respiratory conditions, and diabetes.

Induced impact is calculated by analyzing the expenditures from post-tax salaries by employees. As of 2023, such research initiatives have substantially influenced employment in Malaysia, creating more than 3,500 skilled positions in clinical trial sectors in local hospitals and CROs. The workforce is diverse, encompassing a variety of roles from Principal Investigators (PIs) and Clinical Research Coordinators (CRCs) to nurses, data managers, and administrative staff.

The direct, indirect, and induced economic impact of clinical trials by multinational pharmaceutical companies highlights the foreign direct investment benefits for Malaysia. The total economic contribution from clinical trials in 2023 is estimated at RM 930 Mn , with approximately 80% stemming from indirect and induced impact, illustrating the significant multiplier effect on Malaysia's economy.

1.2 Non-economic contributions

Beyond its economic contributions, clinical trials in Malaysia also deliver significant non-economic benefits that enhance the local healthcare ecosystem, such as opportunities for Malaysian patients to access innovative treatments, opportunities for healthcare professionals to gain exposure to global collaboration and innovation and improved access to high quality data and continuous medical education. The following sections explore how clinical trials and associated activities support the National Industrial Master Plan (NIMP) 2030 and advance Malaysia's commitment to the United Nations Sustainable Development Goals (SDGs).

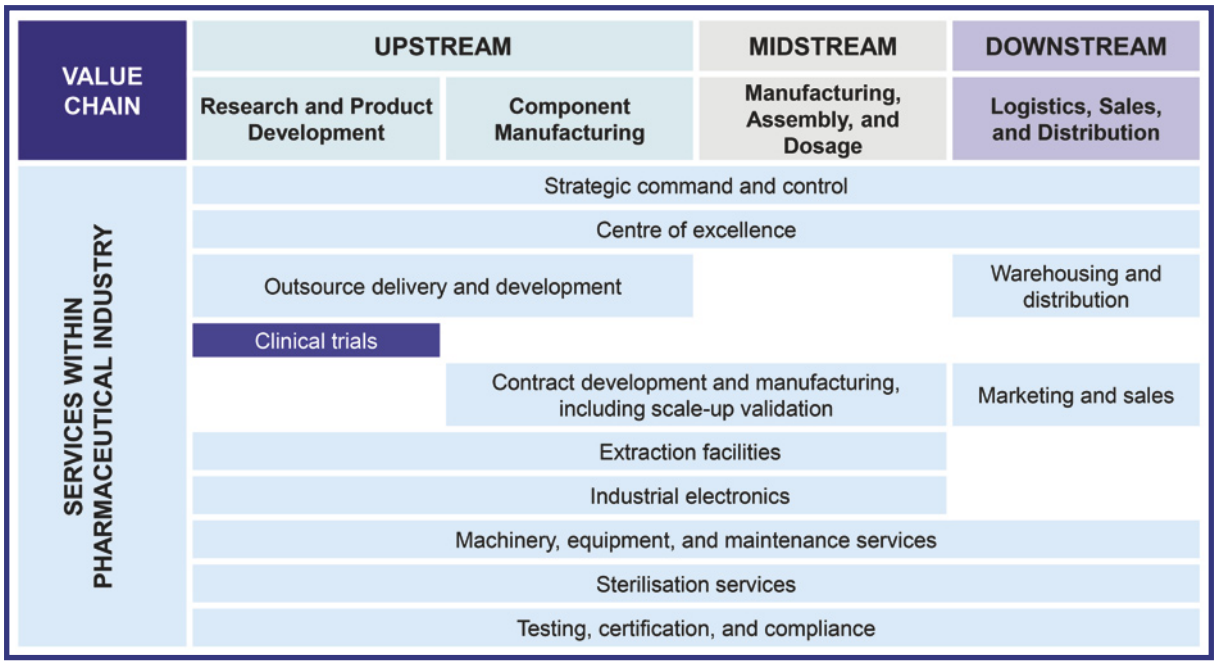
1.2.1 Support for National Industrial Master Plan (NIMP) 2030

Clinical trials are integral to supporting Malaysia's National Industrial Master Plan (NIMP) 2030, particularly as pharmaceuticals and medical devices are identified among the five priority sectors in the 21 plan's sector. Clinical trials directly support Mission 1 of Malaysia's National Industrial Master Plan (NIMP) 2030, "Advance Economic Complexity," by the expansion into high-value-added activities within the pharmaceutical value chain.

As illustrated in Figure 6, clinical trials are positioned among upstream activities, specifically in the discovery, development, and manufacturing phases of pharmaceutical products. This involvement enhances research and product development, leading to the growth of the clinical trial industry, particularly in the development of innovator drugs, vaccines, and biopharmaceuticals [3].

Consequently, there is a growing demand for related services such as Contract Research Organizations (CRO) who provide clinical trial services in the absence of a local pharmaceutical company or related expertise, laboratories, manufacturing facilities, and logistics services. This expansion not only supports the local economy but also aligns with Malaysia's strategic goals of enhancing industrial capabilities and economic complexity through innovation and sophisticated manufacturing processes.

FIGURE 6 Value chain of pharmaceutical industry



Source: New Investment Policy (NIP), Malaysian Investment Development Authority (MIDA)

Additionally, successful clinical trials attract foreign direct investment, promoting knowledge and technology transfer that further stimulates local pharmaceutical sectors and may be a conduit to inspiring local innovation and research. Individuals across the healthcare is also upskilled when exposed to clinical trials working in a global or regional team. The implementation of advanced medical practices and devices introduced through trials also drives innovation in healthcare delivery, supporting the overall modernization of Malaysia's healthcare services.

Moreover, the collaborative environment encouraged by clinical trials through public-private partnerships leads to the establishment of research hubs and innovation centers, catalyzing innovative technologies and entrepreneurial ventures while improving regulatory frameworks to meet international standards, thereby attracting more investors, and enhancing global competitiveness.

1.2.2 Contribution to achieving UN Sustainable Development Goals (SGDs)

Clinical trials play a pivotal role in achieving several United Nations Sustainable Development Goals (SDGs) by advancing global health standards, fostering innovation, building sustainability into clinical trials with reduction in carbon footprint and promoting partnership across stakeholders.

Goal 3 – Good health and well-being

Clinical trials are crucial in achieving several targets of the United Nations Sustainable Development Goal (SDG) 3, which aims to ensure healthy lives and promote well-being for all. By rigorously testing new treatments and interventions, clinical trials advance global health standards, ensuring that medical practices are based on the best available evidence. For instance, they play a vital role in reducing maternal mortality and neonatal and child mortality by developing and validating effective healthcare interventions. Clinical trials also contribute significantly to combating infectious diseases and reducing premature mortality from noncommunicable diseases through the development of new vaccines and therapies. Furthermore, they foster innovation and promote partnerships among governments, healthcare providers, pharmaceutical companies, and patient advocacy groups, which is essential for achieving universal health coverage. This collaborative approach ensures the equitable distribution of healthcare innovations, ultimately supporting the broader agenda of sustainable development and improved health outcomes worldwide. Advancing science from research to commercialization necessitates active collaboration between sponsor and investigators and emphasizes the importance of early exposure to treatment outcomes and practical application. This is exemplified by the commercialization of 15-valent pneumococcal conjugate vaccine, Vaxneuvance by MSD, in Malaysia in 2024. The introduction of this new pneumococcal vaccine offered an additional preventive option for both paediatric and adult populations, creating opportunities for improved health and well-being.

Goal 4 – Quality education

Clinical trials serve as a vital educational platform that enhances research education and promotes professional development within the healthcare sector particularly in the Ministry of Health (MOH) setting where clinical care is prioritized. Increasing clinical trials in the MOH settings, provides medical students, researchers, and healthcare professionals with hands-on experience, clinical trials facilitate a deep understanding of complex research methodologies, patient handling, data analysis, and ethical considerations crucial to medical research.

Moreover, Malaysian doctors have the potential to raise the country's profile on the global stage through their contributions to clinical trials, particularly when selected as co-authors or invited to present at international conferences. Investigators involved in large-scale, multi-center trials with significant participant recruitment are often given the opportunity to be included as authors in related publications. Notable Malaysian contributors in this field include Prof. Wan Zamaniah Wan Ishak (Immuno-oncology study in Gastric Cancer), Dr. Mastura Yusof (Immuno-oncology study on first line treatment for mTNBC), Prof. Ho Gwo Fuang (Immuno-oncology study in second line treatment for Liver Cancer), Dr. Voon Pei

Jye (non-small cell lung cancer), Prof Hatim Sulaiman (Psychiatry in treatment resistant depression), Dato' Dr Mohamed Ibrahim A. Wahid (Quality of life impact in Immuno-oncology study in second line treatment for Liver Cancer), and Prof. Muhammad Yazid Jalaludin (Type 2 diabetes study), who have all made significant contributions to global medical research.

Simultaneously, these trials offer ongoing educational opportunities, allowing healthcare professionals early experience, opportunities to provide input on the development and stay current with the latest to stay current with the latest advancements in medical science and research techniques. This dual focus on experiential learning and continuous professional growth plays a crucial role in advancing the capabilities and expertise of healthcare practitioners.

To demonstrate that the biopharmaceutical industry's commitment to supporting the Malaysian government's Healthcare National Key Economic Areas, companies such as MSD has since 2021 hosted internships with graduating university students who have a keen interest in the industry. The programme has continued to be active and oversubscribed with some interns securing a foothold as permanent employees. Furthermore, there is an increased visibility and global awareness when Malaysian doctors are recognized together with doctors from other advanced and developed countries when they are selected as co-authors or present in international conferences because of their contribution towards clinical trials.

Goal 9 – Industry, innovation, and infrastructure

Clinical trials are instrumental in driving healthcare innovation and enhancing research infrastructure within the healthcare industry. They are pivotal in testing and validating new medical technologies and treatments, directly contributing to technological advancements.

Also, implementing clinical trials often requires the development of specialized research facilities equipped with the latest technologies as there is an expectation that global clinical trials are conducted at a global standard. This investment not only meets the specific needs of clinical trials but also bolsters the overall capacity of the healthcare system to conduct advanced medical research, thereby strengthening its infrastructure and capabilities.

During the Covid-19 pandemic, it was noted that there were several advanced test machines who could be used for Covid-19 available at clinical trial sites who were investigating various respiratory diseases. Clinical trials have also equipped health clinics with generators, additional cabin spaces, and deep freezers to enable clinical research.

As the clinical trial industry grows, there is a corresponding development in innovation through scientific spillovers from prior development of similar therapies that may aid in the development of treatments in other therapeutic classes, particularly for the same disease. Another prime example of the benefits of scientific spillover is the revision of R&D strategies that will be valuable for designing future trials. Demonstrating this, Malaysia became one of the earliest countries in Asia Pacific to have Decentralized Clinical Trial (DCT) guideline, which was launched in July 2023 [4]. This effort was spearheaded by key stakeholders in the clinical trial industry with representatives from PhAMA, reflecting the Malaysia's commitment to advancing modern trial methodologies. Large multinationals such as Novartis, MSD, and Johnson & Johnson have been steadfast in placing clinical trials in Malaysia, as demonstrated by increasing trial volumes year on year, adding investments, and securing Clinical Research Malaysia's prestigious Sponsor of the Year award. This has inevitably influenced Malaysia's research innovation and infrastructure. MSD was honored as the Sponsor

of the Year in 2018, 2019, and 2021. The award for 2020 went to Johnson & Johnson, while Novartis was recognized in 2022. Most recently, AstraZeneca joined the ranks of Sponsor of the Year for its 2023 contributions.

Goal 17 – Partnership for the goals

Clinical trials play a crucial role in driving international collaboration and strengthening policy by requiring multinational partnership that include governments, research institutions, NGOs, and pharmaceutical companies globally. These collaborations are vital for creating a conducive environment for pooling resources, sharing knowledge, and combining expertise to address complex health challenges effectively. Additionally, clinical trials provide opportunity for engagement between regulatory bodies and research entities, which help to harmonize clinical practices and regulatory standards internationally. For instance, two of the earliest site partnerships in Malaysia were established: one between Pfizer and Universiti Malaya Medical Center (UMMC), and another between Novo Nordisk and UMMC. In 2022, Novartis signed a Memorandum of Understanding (MoU) with Clinical Research Malaysia (CRM) on behalf of Sarawak General Hospital (SGH), designating it as a preferred clinical trial site and center of excellence in Malaysia [5]. Meanwhile, AstraZeneca signed an MoU with Sarawak General Hospital (SGH) [6]. Additionally, Novo Nordisk Malaysia who has recently been upgraded to a Clinical Development Centre, establishing it as a regional hub for clinical trial activities across Southeast Asia [7], had signed a MOU with CRM in May 2024 for the joint effort to develop supersites in Malaysia to cater for more trials and more patient contribution [8].

MSD has taken a fresh approach by regularly engaging with CRM and other key institutions through periodic in-person visits from global senior leaders based at the US headquarters, ranging from MSD's Clinical Sciences Study Management to the Global Clinical Trial Operations Senior Vice President. These first-hand experiences and direct facility visits over the years have strengthened Malaysia's reputation as a significant trial contributor and provided Malaysians with access to innovative medicines, with the data speaking for itself: in 2014, a total of 105 patients were randomized, and over the past decade, the number of MSD trials has steadily increased, culminating in a cumulative total of 1,115 patients randomized by 2024. Clearly, MSD has confidence in the clinical trial ecosystem.

These partnerships signify a mutual agreement and desire to grow the clinical trial capabilities at the specific hospital and nation. This partnership aims to strengthen Malaysia's strategic trial sites and expand clinical trial activities across various therapeutic areas, including diabetes, obesity, rare diseases, cardiovascular conditions, and other serious chronic illnesses.

Coming together as a team, Clinical Research Malaysia (CRM) and the Pharmaceutical Association of Malaysia (PhAMA) have signed a strategic MoU in 2024 to enhance clinical trial talent development, with PhAMA providing proteges annually for the next three years [8]. This partnership, inspired by PhAMA and driven by CRM's Centre of Excellence, aims to build skilled clinical trial professionals and align with Malaysia's pharmaceutical R&D goals under the New Industrial Master Plan 2030 and to support the skilled talent needs that align with the growth in the clinical trial sector.

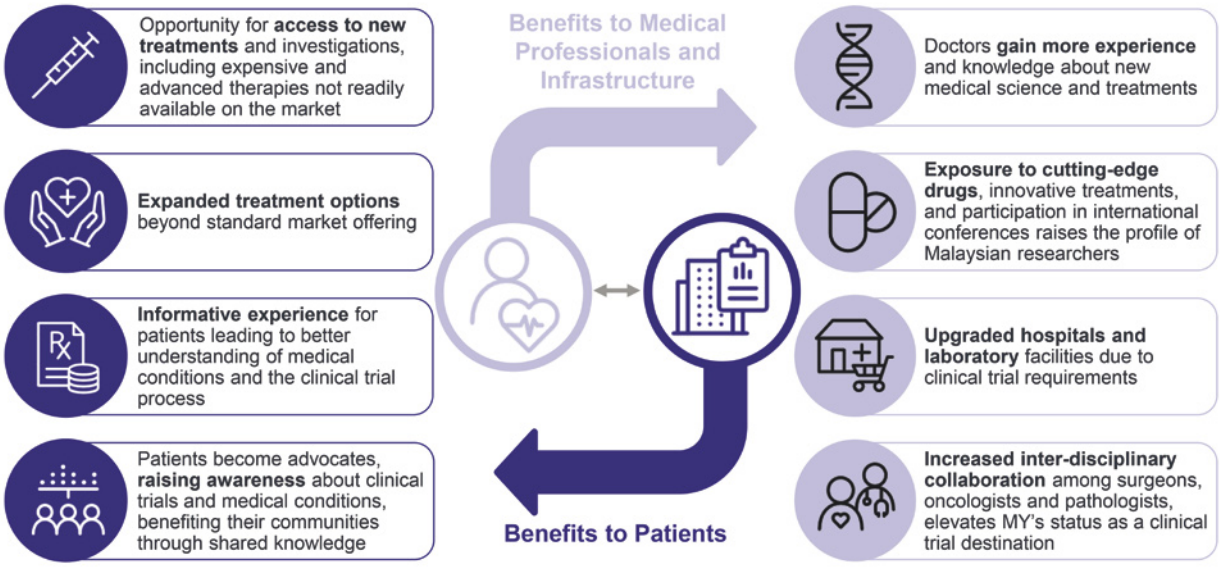
"Partnerships in clinical research will help drive the future of Malaysia's clinical trials, accelerate the pace of innovation and ensure that breakthroughs reach those who need them most — the patients. This will undoubtedly pave the way for a healthier tomorrow"

— EeLaine Tan,
Country Head Malaysia, Global Clinical Operations, Johnson & Johnson

Benefits of clinical trials: Insights from experts and patients

The journey of clinical trials is important for the country but is also personal and often challenging for both the healthcare professionals and patients. To shed light on its importance, we interviewed five doctors and four patients in July-August 2024 who shared their experiences and insights on the benefits of clinical trials.

> "Clinical trials in Malaysia have a bright future, supported by strong infrastructure, skilled researchers, and committed healthcare providers. With increasing trials and collaboration, we aim to initiate more local studies and enhance public awareness, positioning Malaysia as a prime destination for clinical trials."
>
> — Dr T. Rheumatology



Source: IQVIA

DR D
ONCOLOGY

Doctor D has always viewed clinical trials positively, seeing them as beneficial for patients and the healthcare system alike. For patients, these trials offer access to advanced treatments not yet available on the market, enhancing their understanding of their conditions and the broader healthcare system.

Moreover, clinical trials serve as a crucial learning platform for doctors, allowing them to gain experience with new therapies and expand their scientific knowledge. This not only improves the level of medical care but also prepares healthcare professionals to better address complex medical challenges with the latest advancements.

"I remind my patients that by participating in clinical trials, they're not just helping themselves, but also advancing medical science. They contribute to a legacy that could benefit future patients facing similar battles."

DR T
RHEUMATOLOGY

Dr. T emphasizes the benefits of clinical trials for both patients and healthcare providers. He notes that clinical trials provide patients with access to new treatments and healthcare providers with opportunities for further training and advancements in medical knowledge. Dr. T has observed high satisfaction among participants, with many expressing a desire to continue even after the trials concluded.

To encourage participation, Dr. T carefully explains the pros and cons of clinical trials, stressing that involvement is voluntary and ultimately the patient's decision. He respects each patient's final decision regarding their participation in clinical trials.

"In the past decade, Malaysia has made significant strides in clinical trials, positioning itself to become a leader in the Asia Pacific region with its strong patient base and established infrastructure.

DR S
RHEUMATOLOGY

Dr S is driven to recruit patients for clinical trials by his commitment to enhancing patient health and achieving recruitment targets. Dr S view clinical trials as vital for advancing medical research and improving patient care. By focusing on the long-term benefits for participants, Dr S remain optimistic about the future of clinical trials in Malaysia. The 95% patient adherence rate in these trials in Malaysia, supported by diligent monitoring and follow-up by study coordinators, indicates a high level of patient satisfaction.

Additionally, recent infrastructure improvements made by Clinical Research Malaysia (CRM) have significantly bolstered Malaysia clinical trial capabilities, further bridging the gap between clinical trials and patient welfare. This enhanced infrastructure not only supports our operational goals but also elevates the overall patient experience, fostering greater engagement and satisfaction.

DR L
NEPHROLOGY

Dr L has been involved in clinical trials for nearly 20 years, starting with sub-investigator then principal investigator. To him, clinical trials are one of the important ways we advance our knowledge in newer interventions towards better clinical care. When he started, he viewed clinical trials as time consuming and resource intensive, but now he feels that the importance of clinical trials is beyond advancement of medical knowledge and seeking new options for patients, but also important for clinicians to stay up to date on the development of science in specific area. Many patients attending the care are more educated and more receptive to the idea of participating in future new studies.

"One remarkable story involves a dedicated patient from Penang who traveled to Kuala Lumpur for every appointment of her IgA nephropathy trial. Despite the distance, she preferred our center, trusting us completely with her care. After successfully completing the two-year follow-up, she's now eager to continue with the trial's extension phase. Her commitment and trust are truly inspiring."

DR M
ONCOLOGY

Dr. M has been a Principal Investigator since 2009, after starting as a Co-Investigator in 2003. He notes that half of his patients are satisfied with their clinical trial outcomes. For instance, one patient, initially assigned to a chemotherapy arm in a randomized, blinded study, opted to self-finance access to immunotherapy after learning of positive outcomes from another trial arm. Dr. M emphasizes the importance of patient data in contributing to national progress and future scientific advancements.

In addition, Dr. M advocates for increased investment and accreditation of molecular labs in Malaysia to enhance the efficiency of clinical trials involving molecular testing and targeted therapy. He is keen to see more clinical trials conducted in Malaysia, urging pharmaceutical companies to consider broader benefits beyond investment, such as enhancing patient access to medicines, including for adjuvant therapy and not solely for metastatic stages. Additionally, Dr. M hopes for an uptick in trials involving targeted molecular therapies and foresees greater inter-disciplinary collaboration among healthcare professionals like oncologists, surgeons, radiotherapists, and pathologists, which he believes will enhance the quality of clinical trials.

"Back in 2015, the survival expectation for stage 4 triple-negative breast cancer patients was about one year. However, through their participation in the Keynote clinical trial, which provided access to immunotherapy, the outcomes have been remarkable. Of the 15 patients enrolled, more than 5 are still alive today, far exceeding the initial survival projections."

" I faced challenges with the Keynote-119 study due to manpower shortages. Thanks to CRM's assistance in providing a coordinator, I was able to successfully conduct the Keynote 355 study."

PATIENT R
BREAST CANCER

48 years old, Teacher
Pantai Hospital, Kuala Lumpur

Patient R battling metastatic Triple-Negative Breast Cancer (TNBC), discovered clinical trials through a friend, a fellow cancer fighter and professor. Initially, Patient R had little information about clinical trials but was drawn to the promise of immediate treatment and better chemotherapy options. She researched and consulted oncology specialists, deciding positively to participate.

Since joining the trial, Patient R has gained confidence in the treatment regimen, experiencing fewer side effects, and seeing positive results in her CT scans. Motivated by a poor prognosis and limited life expectancy, she chose to contribute to a trial that could benefit future patients. Rating her experience a perfect 10, she appreciates the high quality of care and has been NED (No Evidence of Disease) since 2017.

Participation has significantly impacted her health and well-being, providing access to new drugs and specialized treatments. However, challenges included travel costs, frequent hospital visits, and her husband taking unpaid leave. She overcame these difficulties by taking a personal loan, staying with relatives, and relying on family support.

Patient R would consider future trials, valuing the quality of treatment and care. She advises other patients to participate if eligible, viewing it to help advance medical treatments and as a form of ongoing charity. She highly recommends clinical trials with a perfect score of 10 out of 10.

"Participating in the clinical trial was transformative. The treatment has fewer side effects and has shown positive results, allowing me to live beyond my expected prognosis. I'm grateful for the high-quality care and encourage others to consider clinical trials, as they offer hope and potentially lifesaving options."

PATIENT A
PSORIATIC ARTHRITIS

42 years old, General Manager at an NGO
Selayang Hospital, Selangor

Patient S was being introduced and was referred for a clinical trial. Her initial hesitance stemmed from a lack of understanding about clinical trials. However, the research team's dedication and thorough explanations soon dispelled her concerns, providing her with a clear and reassuring perspective on the process.

Having struggled with ineffective treatments in the past, Patient S was in desperate need of a more effective solution for her condition. The clinical trial offered her a new of hope with a drug that promised not only to alleviate her symptoms but also to improve her overall quality of life. The trial had a transformative impact, greatly improving her health and enabling her to reclaim a sense of normalcy and joy in her daily life.

Patient S is particularly appreciative of the supportive research team whose expertise and care turned her treatment journey into a positive experience, despite some minor side effects. She noted the effectiveness of the treatment as a key factor in her recovery and would unhesitatingly recommend the clinical trial to others, rating her likelihood to endorse it a full 10 out of 10.

The journey did have its challenges, though. The registration process was a bit overwhelming, and the need for frequent hospital visits meant sacrificing important work hours. Luckily, her employer was flexible, which made it easier to handle these hurdles without too much stress.
One area for improvement that Patient S highlighted was the need for better accommodation options for caregivers and patients coming from outside the Klang Valley area. While the research team performed admirably within their scope, she felt that enhancements in hospital facilities to support caregivers could further ease the burden for participants traveling long distances for treatment.

CHILD PATIENT
(comment by child's mother)
RARE IMMUNOLOGY DISEASE

5 years old
UMMC, Kuala Lumpur

In 2022, faced with her child's rare immunological disease and heightened risk of COVID-19 infection, the patient's mother learned from a pediatrician about an ongoing clinical trial recruiting pediatric participant. After careful consideration, she decided it was best for her daughter to join the trial, which offered access to a COVID-19 vaccine. Consequently, her daughter was referred to UMMC to participate in the trial.

The clinical trial at UMMC operated efficiently, earning an overall satisfaction rating of 8 out of 10. However, one challenge noted was follow-up via text, which could be improved by using phone calls for more thorough communication and comprehensive data collection. The study coordinator handled processes promptly, and patient reimbursements were issued immediately. Patients received close monitoring and clear instructions on their treatment protocol. Most importantly, the principal investigator took the time to patiently address all questions, ensuring thorough understanding and comfort for the patients.

Clinical trials can provide access to additional treatment options. The quality of the service and qualifications of doctors plays a vital role in giving me the assurance to join clinical trials in the future. Clinical trials may not be suitable for everyone, I would recommend based on the patient's clinical need, and the potential of the investigational product.

"This trial not only protected my daughter during the pandemic but also allowed her a semblance of normal childhood activities like attending kindergarten and playing outdoors."

PATIENT M
DIABETES

81 years old, Retired
UMMC, Kuala Lumpur

Patient M first heard about clinical trials from a professor at the university hospital, her understanding of what they involved was quite limited. It was only after learning more that she realized the commitment required, including close monitoring such as tracking daily steps with a pedometer—something far different from her initial expectations.

Patient M joined the clinical trial primarily to improve her health, aiming for a healthier weight and better control of her diabetes. The trial offered frequent monitoring every three months, supervised through a detailed logbook. This structured approach and the hope for better health motivated her to participate. The impact was significant, helping her maintain better control over her diabetes and manage her weight more effectively.

For anyone considering a clinical trial, it's crucial to thoroughly read and understand the consent form. Discussing it with family members can provide additional perspectives and support. It's important to fully grasp the commitment and potential consequences before agreeing to participate. Signing up just to please a professor can lead to challenges down the line, including the possibility of withdrawing due to a lack of commitment or misunderstandings with healthcare providers.

Clinical research in Malaysia plays a crucial role in advancing medical science and improving patient care.

- **Access to advanced treatments:** Receive innovative treatment with potentially fewer side effects than standard options.
- **High quality care:** Benefit from top tier medicines, facilities, and healthcare professionals for exceptional patient care.
- **Close monitoring and support:** Enjoy thorough monitoring, efficient study coordination, and prompt reimbursements, ensuring smooth experience.
- **Contribute to medical advancements:** By participating, patients help advance medical research, potentially benefiting future patients with improved treatment options.

This is an illustrative case that highlights the common benefits from patients in the Clinical research space in Malaysia

CHAPTER 2:
The evolution of Malaysia's clinical trial sector

Since the early 1990s, Malaysia has been participating in clinical trials, predominantly sponsored by global pharmaceutical and medical device companies. We shall look at the headways and milestones achieved across the journey leading up to Malaysia's strong position in clinical trials today. These advancements are the result of collaborative efforts between the government and the private sector, whose dedication has been key to Malaysia's success.
Pre-2000s: Laying the foundation

In 1999, the Ministry of Health (MoH) introduced the first Malaysian Guidelines for Good Clinical Practice (GCP), setting the stage for a robust clinical trial environment [9]. These guidelines were crucial in ensuring that clinical trials conducted in Malaysia adhered to international standards, thereby gaining global recognition and trust. In the early days, there was limited skilled clinical trial workforce and clinical trial monitors often came from Singapore and other countries.

2000-2005: Building capacity

The early 2000s saw the establishment of the Institute for Clinical Research (ICR) in 2000 [10], aimed at streamlining clinical trials and building clinician research capacity. Industry and government partnerships were also key in driving maturity growth of clinical trials, with multinational pharmaceutical companies such as Novo Nordisk playing an active role in clinical trials since 1999 and Johnson & Johnson since 2005 [11]. This period marked the beginning of structured efforts to enhance Malaysia's clinical trial capabilities. During this period, most of the clinical trials conducted were phase III and IV clinical trials where a larger patient population is required. Malaysia had less opportunities to run early phase trials in phase I and II due to the competitive clinical trial landscape and capability readiness then.

2006-2010: Streamlining processes

From 2006 to 2010, there was significant growth in clinical trial outsourcing in Malaysia, largely driven by the rise of contract research organizations. During this period, several pharmaceutical companies began shutting down their R&D teams in the country, responding to shifts in the pharmaceutical business landscape.
By 2010, the Entry Point Project for the Healthcare National Key Economic Area (NKEA) was launched [12], emphasizing the crucial role of clinical trials in the country's economic strategy and urging collaboration among stakeholders to support the initiative. The NKEA set goals of 1,000 clinical trials and 1,000 skilled jobs by 2020; however, by 2015, there were already 1,118 high-skilled jobs created, demonstrating early success in the sector.

2011-2015: Institutionalizing clinical trials

The Pharmaceutical Association of Malaysia's contribution to the Economic Transformation Program (ETP) Entry Point Project (EPP) 2 White Paper published in 2011, played a critical role in fostering partnerships between all key stakeholders – including multinational pharmaceutical companies, Clinical Research Organizations (CROs), and Clinical Research Malaysia (CRM) [13].

This period also saw the first revisions of the GCP guidelines in 2011, reflecting local regulatory requirements and advancements in clinical trial practices. The establishment of Clinical Research Malaysia (CRM) in 2012 by the MoH, aimed to bring clinical trials that addresses the unmet needs of patients and transforms health outcomes in Malaysia.

During the development of Malaysia's Economic Transformation Program (ETP), PhAMA produced a pivotal white paper outlining recommendations to strengthen Malaysia's clinical research sector.

The white paper provided a strategic vision for the Clinical Research Centers (CRC) and Clinical Research Malaysia (CRM), emphasizing the importance of enhancing research infrastructure, increasing the number of high-quality research sites, and building a skilled clinical research workforce. The paper underscored the need for streamlined processes and improved regulatory timelines, which could elevate Malaysia's competitiveness in attracting global clinical trials. PhAMA's insights and guidance were instrumental in identifying key actions for CRM, such as creating incentives for researchers, developing comprehensive training programs, and fostering industry collaboration to position Malaysia as a leading destination for clinical research in Asia.

2016-2021: Advancing Early Phase Trials

Seeking to remain competitive and expand the clinical trial horizons, CRM looked to expand early-phase clinical trials in Malaysia, in 2016, CRM and the MoH developed the Phase I Realization Project (P1RP) [14]. This five-year plan aimed to enhance Malaysia's capabilities in conducting early phase, including First-in-Human (FIH) trials. Key developments during this period included the launch of the Malaysian Phase 1 Clinical Trial Guidelines (MP1CTG) in 2017 [15], the establishment of the Scientific Review Panel (SRP) for Phase 1 in 2018 [14], and the accreditation of the first facility (Sarawak General Hospital) under the Phase 1 Unit Accreditation Program by the National Pharmaceutical Regulatory Agency (NPRA) in 2019 [14].

"Malaysia's clinical trials journey has shown significant growth and development, evolving into a key player in global research through innovation, expertise, and commitment to advancing healthcare"

— Yeap Lay Ee
Associate Director,
Clinical Operations MSD

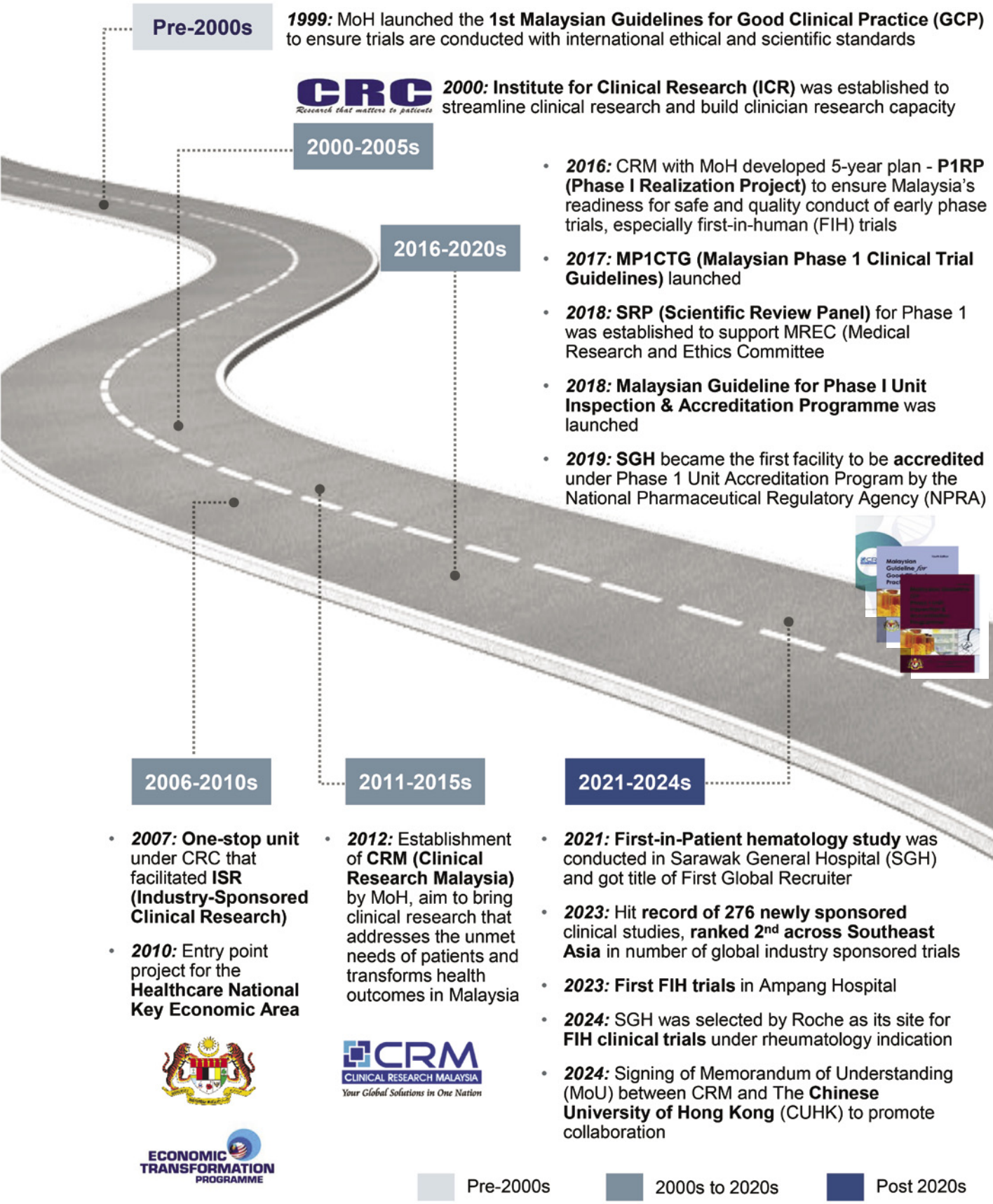
2021-2024: Achieving global recognition

The recent years have been marked by significant achievements on a global stage. 2019 onwards saw growth and involvement in R&D for multinational pharmaceutical companies in Malaysia, such as the re-establishment of the AstraZeneca Clinical Research team (2022), Eli Lilly's regional APAC Trials Capabilities Hub (2019), and Novo Nordisk's Regional Hub (2024). In 2021, the first First-in-Patient hematology study was conducted in Sarawak General Hospital (SGH), led by Dr. Chew Lee Ping. The study performed exceedingly well, with Dr. Chew's team being the first to enroll patients ahead of other global sites [16]. By 2023, Malaysia hit a record of 276 newly sponsored clinical studies, ranking second across Southeast Asia in the number of global industry-sponsored trials [17]. Prior to this, Malaysia had been in third place behind Thailand and Singapore for many years.

Collaborations from both industry and Clinical Research Malaysia (CRM) resulted in the birth of Malaysia's first FIH trials in Ampang Hospital in 2023 [16], and the selection of SGH by Roche for FIH clinical trials under rheumatology indication in 2024 further solidified Malaysia's position as a leader in clinical trials [18]. Moreover, a Memorandum of Understanding (MoU) was signed with The Chinese University of Hong Kong (CUHK) in 2024 to promote further international collaboration [19]. In 2024, CRM also signed MoU with SCRI to drive research collaboration. Other MoU's signed to drive capability development in the space of FIH include with National Cancer Centre Japan (2020) and Princess Margaret Cancer Centre (2022).

In addition, Clinical Research Malaysia (CRM) and the Pharmaceutical Association of Malaysia (PhAMA) have entered a strategic partnership aimed at boosting the development of clinical trial talent through CRM's Centre of Excellence (CoE) [20]. This initiative focuses on building a skilled workforce of study coordinators and advancing Malaysia's clinical trial capabilities.

FIGURE 7 Journey of clinical research sector in Malaysia (1999-2024)



NOTE: In 2019, the Clinical Research Centre (CRC) was changed to Institute for Clinical Research (ICR) when five research institutions (including CRC) under the Ministry of Health was administratively placed under the National Institute of Health (NIH).

The journey of clinical trials in Malaysia has been marked by investigators with foresight. Malaysian representatives in pharmaceutical companiesexecutedthroughstrategicinitiatives, capacity building, global collaboration, and recognition. As we celebrate the significant advancements and developments in clinical trials in Malaysia, there are several levers that can propel Malaysia's clinical trial landscape into being more globally competitive. These will be discussed in detail in the following section.

2.1 Developing infrastructure

In 2023, Malaysia achieved a record of having 259 clinical trial sites [21]. To support growth towards the next step, infrastructure development is a key lever that Malaysia can tap into to emulate the success and maturity of other developed APAC markets such as South Korea or Taiwan.

2.1.1 Investing in testing equipment in less developed testing centers

As Malaysia hits a new milestone of 259 clinical trial sites in 2023, there remains further opportunities for Malaysia to gain global competitiveness through investing in well-equipped trial sites. While key hospitals such as Sarawak General Hospital (SGH) and Ampang Hospital possess specialized infrastructure that supports complex and innovative clinical trials, including FIH trials, other sites in Malaysia have room for improvement. This is particularly evident in their ability to cater to the rapidly growing oncology clinical trial sector.

As Malaysia strives to be equally competitive as other mature APAC countries such as South Korea, investments in testing equipment such as advanced imaging technologies can help boost the country's capabilities in conducting more trials, and trials that are higher in complexity. Currently, in comparison to South Korea's MRI density (unit per million population) of 35.48, Malaysia stands at 3.56 units per million population (or 121 MRI units across the country as of 2022) [22] [23].

Malaysia can also stand to emulate the efforts of other more mature healthcare markets, in investing in more dedicated clinical trial facilities, which include specialized laboratories and testing such as biomarkers for oncology, secure storage for biological samples, and advanced diagnostic tools. This will enable Malaysia to take on a wider and / or more advanced range of clinical studies. Especially by investing in the rural regions, this will narrow the urban-rural divide and enable patient recruitment from more diverse demographics. Hematogenix, a global central laboratory for oncology which has its facility set up in Cyberjaya, is a notable example.

Moreover, the high concentration of clinical trials in a few key centers strains their capacity and their capacity and could potentially impact clinical trial quality when capacity exceeds capabilities. However, this situation also presents opportunities to expand and develop these centers into hubs of clinical trial excellence. By addressing both the need for improved infrastructure and the distribution of trial sites, Malaysia can ensure growth and enhance its standing in the global clinical research landscape.

2.1.2 Standardizing medical record management

Standardization of data collection, storage, and reporting standards across different trial sites will minimize inconsistencies and enhance the integrity of clinical trial outcomes.
However, opportunities still exist, especially in the rural regions, such as the adoption of Electronic Medical Records (EMR). While urban hospitals might have advanced digital systems, many rural and smaller clinics still rely on paper-based records, making data consolidation and analysis cumbersome. By closing the urban-rural gap, Malaysia can enhance data management efficiency, leading to better analysis, improved research outcomes, and more informed decision-making.

Building onto the headway made in EMR proliferation within urban hospitals, it is important to extend the ability to store, manage and share data effectively and efficiently with clinical trial providers. To achieve this, more efforts to integrate IT systems necessary for clinical trials, such as a robust IT infrastructure that supports secure data sharing and real-time access patient information, is required.

Investment in this area can lead to less delays in trial timelines, reduced costs, and better accuracy in trial results.

Standardizing medical record management in clinical trials brings substantial benefits, particularly in recruitment and site selection. With a unified system, trial organizers can predict recruitment rates with greater accuracy based on reliable data on disease prevalence and patient demographics. This allows for smarter site placement, ensuring trials are conducted in areas with higher patient concentrations, ultimately saving time and reducing recruitment costs. Additionally, standardized records streamline patient matching by enabling precise filtering of eligible groups according to complex trial criteria, accelerating the enrollment process.

For patient care, standardized records improve management, especially as clinical trials increasingly focus on patients with multiple conditions. Physicians gain a complete view of a patient's history, enabling better care and ongoing monitoring. This is crucial as trials grow more complex, requiring doctors to have centralized access to comprehensive information. Hospitals also benefit, as transitioning to electronic records alleviates space constraints for physical storage, while reducing administrative burdens and minimizing data loss risks.

Beyond these logistical advantages, standardization enhances data integrity, lowering the risk of errors and providing consistent, high-quality data for regulatory compliance and trial outcome reliability. Access to real-time data also allows for faster, more responsive decision-making, especially for adaptive trial designs that adjust protocols mid-trial. Centralized data contributes to patient safety by flagging potential drug interactions, allergies, and adverse reactions, ensuring compliance and prioritizing patient welfare.
Standardization supports broader research goals as well. With shared formats across sites, data aggregation and analysis in multi-center trials become seamless, facilitating collaboration. In the long term, standardized records pave the way for follow-up studies and longitudinal research, allowing data to be reused effectively for future trials, thereby advancing the broader healthcare and research ecosystem.

2.2 Develop new investigators and research facilities

2.2.1 Investing in investigators development

Qualified and experienced investigators are essential for conducting high-quality clinical trials, as they play a critical role in overseeing the study team, ensuring proper trial conduct, and safeguarding patient safety [24].

Whilst Malaysia has seen a growth in investigators, this growth is superseded by demand for investigators, presenting opportunities to develop new investigators or research facilities. Figure 8 shows that between 2017 and 2021, the annual growth rate of new investigators in clinical trials was 2.9%, whilst the growth rate of sponsored research trials was higher at 4.3% per year. This discrepancy suggests an unmet need for the availability and an implied probability that existing investigator's workload increased to support the capacity of new clinical trials of qualified investigators to cater to the increasing demand for clinical trials. Through developing new investigators and clinical research support staff, Malaysia can mitigate any potential challenges in maintaining the quality and oversight of its clinical trials, allowing it to stay globally competitive. Multinational pharmaceutical companies in Malaysia have supported the pharmacist rotation programme and clinical trial exposure is one of the rotation modules.
According to the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH E6) Good Clinical Practices (GCP), it is mandatory for all investigators to be GCP certified and have experience in conducting clinical trials [25]. However, the implementation of training programs and curricula remains unstandardized, leading to inconsistencies in training quality and preparedness among investigators. There is an opportunity to enhance the GCP training of the clinical research workforce through a standardized training plan.

To further grow talent in the clinical trial field, Malaysia can consider assessing its current training programmes to assess the gaps, additions and enhancements needed to equip potential professionals with the necessary skills and knowledge to navigate the complexities of clinical trials.

Efforts to elevate the number of academic clinicians with explicit research publications and responsibilities in medical schools beyond the major teaching hospitals like HUSM, HCTM, and UMMC is also recommended [26] Protected time for investigators at least once a week or a suitable duration is recommended to encourage investigators particularly in the MOH setting to be able to balance both clinical and research work. Protected time is not a new recommendation but there are still barriers in applying this in the real clinical setting.

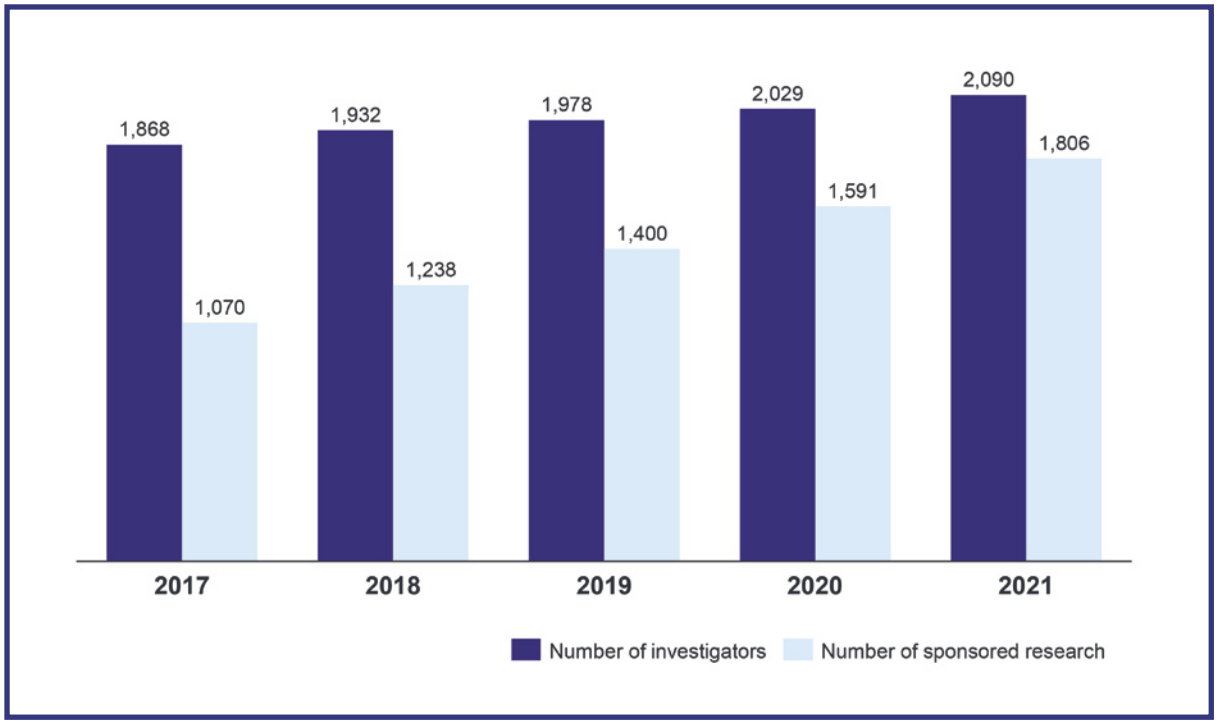
Clinicians in these other schools have limited access to dedicated university hospitals, thus relying on state government hospitals for teaching purposes. With the growing number of medical students, enabling other medical schools to equally qualified academic clinicians will help increase the capacity of academics in conducting and contributing to meaningful research. This would boost Malaysia's quality of clinical trials, training, and development of future medical professionals in clinical trials.

2.2.2 Strengthening secondary support functions

While the role of qualified investigators is central to clinical trials, secondary support functions - such as research coordinators, pharmacy teams, and hospital administrative support are equally essential in building a globally competitive workforce. Research coordinators handle key logistical aspects, including patient recruitment, data collection, and regulatory compliance, ensuring smooth trial operations. Pharmacy teams play a critical role in managing and dispensing trial medications, maintaining drug integrity, and ensuring adherence to safety protocols. Additionally, support from hospital administrators and directors facilitates resource allocation, streamlines approval processes, and fosters a research-friendly environment.

By investing in these secondary support roles, Malaysia can create a well-rounded support system that enhances clinical trial efficiency, improves patient care, and ultimately contributes to the nation's competitiveness in the global clinical research landscape.

FIGURE 8 The cumulative growth of skilled jobs in clinical research involved in ISR (2017-2021)



Source: Clinical Research Malaysia

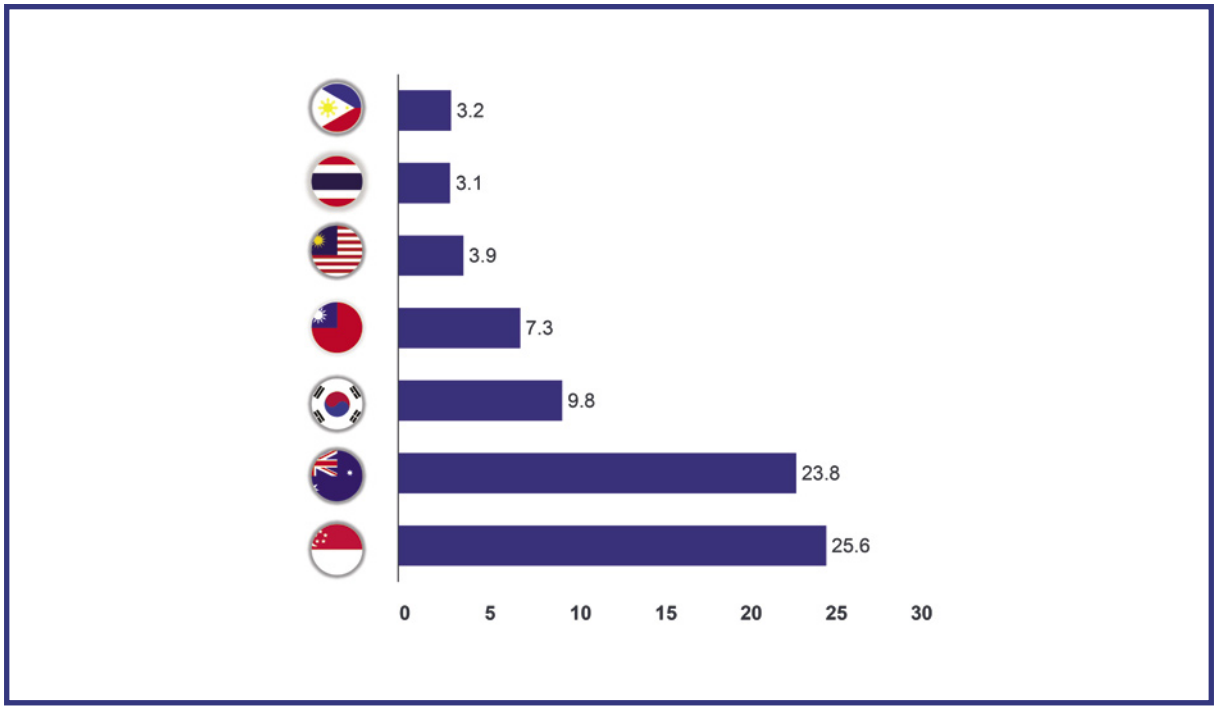
2.2.3 Lowering barriers and incentivizing specialists

According to Figure 9, Malaysia has fared better with a higher oncologist to doctor ratio compared to countries in the region, such as Philippines. Moving forward, Malaysia should aim for a higher doctor to population ratio in in key sectors such as in oncology and cardiology, such as seen in other developed APAC markets. Currently, there is a low specialist to population ratio, with only 133 oncologists and 300 cardiologists practicing amidst rising incidences of these diseases [27]. Among these specialists, only 26% of oncologists and 10% of cardiologists are employed in public hospitals [34]. Amidst the trend of oncologists moving from public to private practice, this might lead to a depletion of resources in public healthcare settings where most clinical trials are conducted.

To mitigate this issue, it is suggested that engagement and resource allocation barriers that can significantly impact doctors' participation in clinical trials are lowered. Lack of interest in the research process, coupled with limited time due to heavy clinical duties, prevents many physicians from becoming active in research, thereby constraining the advancement and diversity of medical studies.

Additionally, shaping the perception and institutional recognition of clinical trials at the hospital director or doctor/physician level may further improve the situation. In Malaysia, clinical trials often do not receive the same level of importance as clinical service [28]. Although this issue is not unique to Malaysia, elevating the cultural and systemic valuation of research will incentivize specialists to engage in research activities. This is particularly important in the public sector, where the immediate need for clinical services can overshadow the long-term benefits of research involvement. A boost in emphasis on research within the healthcare system can grow both the development of new treatments and the potential for clinical advancements.

FIGURE 9 Number of oncologists per 1 million population in different countries (2022)



Source: Statista, ASCO, Thai Society of Clinical Oncology, Taiwan Cancer Registry

2.3 Lowering barriers to study start-up

2.3.1 Streamlining clinical trial agreement and budget review process

Typically, the negotiation of Clinical Trial Agreements (CTA) and budgets tend to be significant bottlenecks in initiating clinical trials [29]. This is largely due to bureaucratic processes and ineffective communication protocols. Aligning and streamlining the agreement processes pertaining to CTAs and budgets can help expedite review period by a factor of 3-4 times.

A CTA as defined in The Malaysian Guideline for Good Clinical Practice is "a written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract."

Historically, from 2012 to 2015, the Legal & Regulatory Affairs department required an average of 59 days to review and endorse a CTA [29]. However, following the implementation of a new system in March 2016, the review period was dramatically reduced to just 14 days [29]. This significant improvement highlights the potential benefits of systematizing and streamlining legal processes within the regulatory framework.

2.3.2 Expediting regulatory and ethics committee processes

Whilst Malaysia has made improvements in the area of streamlining clinical trial start up process, to remain competitive against other mature markets, and strengthen its appeal as a preferred destination for clinical trials, there is a need for Malaysia to continually refine its regulatory process to enhance the efficiency of its clinical trials landscape without sacrificing the standards.

Table 2 illustrates that recent timelines for regulatory and ethics approvals in various countries have become faster, highlighting a global trend towards efficiency. Malaysia can draw on the examples from other countries in the region, to streamline its regulatory process.

For example, Australia provides an example of how regulatory processes can be made more efficient, through its Clinical Trial Notification (CTN) scheme, which typically processes approvals for most interventional trials in just five to ten days [30]. This scheme, used primarily for clinical trials involving chemical drugs and biological products deemed low to medium risk, allows for greater flexibility without compromising the quality or ethical standards of the research. Additionally, the data from Australian trials are recognized globally and can support international regulatory applications, including take hose for the US FDA Investigational New Drug (IND), thereby enhancing the efficiency of clinical trials conducted in Australia [31].

TABLE 2 Regulatory and ethics timeline

Countries	Timeline		Submission
	Regulatory	Ethics	
Singapore	~ 30 days	~ 30 days	Parallel
Malaysia	**~ 30 days**	**~ 50 days**	**Parallel**
South Korea	~ 30 days	~ 50 days	Parallel
Hong Kong	30-60 days	30-60 days	Parallel
Japan	Approval is by default if no objections within 30 days	4-8 weeks	Sequential
Taiwan	~ 30 days	30-60 days	Both
Australia	~ 30 days	4-6 weeks	Parallel

Source: Pharmaphorum, 2016

Similarly, the Chinese government has significantly reduced its approval time from 265 days to 65 days, demonstrating proactive efforts to streamline processes [32].

Moreover, to ensure that ethics approval processes can be made more efficient and therefore ensuring that trial start up is smooth, Malaysia can consider further support for the ethics committee.

Securing ethics approval from the Medical Research and Ethics Committee (MREC) and regulatory approvals from the National Pharmaceutical Regulatory Agency (NPRA) for clinical trial import licenses or exemptions is essential but can be time-consuming, hence a streamlined and consistent process can reduce the time and increase competitiveness. In 2017, the Ministry of Health (MOH) mandated that all Ethics Committee and Institutional Review Boards (IRB) involved in approving drug-related clinical trials must register with the National Pharmaceutical Regulatory Agency (NPRA), the secretariat for the local Drug Control Authority (DCA) [33].

This requirement could, in some cases, act as a bottleneck in the clinical trial setup, impacting overall timelines and milestones. Delays can occur as committees either seek external expertise or require additional time to adequately assess specialized or complex proposals. The complexity of the notion of risk, as well as the uncertainty of the potential benefits of research, make the process of risk/benefit assessment a significant challenge for research ethics committees. Additionally, the varying requirements and preferences of different ethics committees further complicate the process, as sponsors must navigate and accommodate each committee's specific standards and expectations.
While most ethics committees are generally well-composed in terms of specialty representation, they may still face challenges due to the wide variety of research projects they review.

One of the key challenges faced by the Ethics Committees (ECs) in Malaysia is the increasing number of institutional ECs, each with unique requirements. This diversity results in varying submission processes—some committees require paper submissions, while others operate electronically. Additionally, differences in fee structures, with some ECs charging fees and others operating without, further complicate the process. The frequency of meetings and the types of documents required for review also vary widely among committees, creating additional layers of complexity for researchers and sponsors. This lack of standardization can slow down the approval process, impacting the overall efficiency and timeliness of clinical trials in Malaysia. While the establishment of the Network of Ethical Review Committees in Malaysia (NERCIM) aims to harmonize ethics review among all IRBs/IECs in Malaysia, more support can be given to committees which may not have adequate expertise in certain specialized areas or research methodologies, to minimize delays in the review process. By providing more support to the ethics committee, Malaysia can boost the efficiency and effectiveness of the clinical trial approval process, positioning it as a globally competitive player in the advancement of important medical research.

CHAPTER 3:
Leading the way: Transforming clinical research in Malaysia

In 2024, Malaysia unlocked a new milestone of coming first in Southeast Asia for number of industry-sponsored studies ahead of Singapore and Thailand after being third and then second for the last 5 years [17]. Additionally, Clinical Research Malaysia (CRM) has set a new goal of reaching 4,000 new sponsored research projects by 2033 [21]. Additionally, in a recent 2024 IQVIA report "Rethinking Clinical Trial Country Prioritization", Malaysia was ranked among the Top 30 countries globally and 1st in Southeast Asia for country readiness in global clinical trials.

While significant progress has been achieved, continuous resources and efforts will be required to sustain and maintain the current growth momentum Malaysia has achieved now to meet the new target.

When multinational pharmaceutical companies assess locations for conducting clinical trials, they consider key factors such as:

a) Trial performance (speed and quality)

The speed at which a clinical trial can be initiated varies by country, influenced by institutional, ethical, and regulatory requirements. For example, in the USA, the start-up process can take several weeks to months due to comprehensive reviews and approvals. Efficient patient enrollment, characterized by low deviations and withdrawals, is crucial for high-quality data. Countries with streamlined set-up and activation timelines, and effective patient recruitment and retention strategies, including diversity and rare disease recruitment, are preferred.

b) Relevant Expertise /Expertise Network

Qualified and experienced investigators are essential for conducting clinical research. Investigators must be well-versed in clinical protocols and regulatory requirements. Additionally, a competent local clinical operations and monitoring workforce supports the efficient conduct of trials. Countries with a strong network of trained investigators and clinical operations staff are more attractive for clinical trials.

c) Regulatory framework

Multinational pharmaceutical companies prioritize countries with efficient and welcoming regulatory frameworks for conducting clinical trials. Effective regulatory environments facilitate faster approvals and smoother operations, which are critical for bringing new compounds to market. Clear registration and approval policies are essential for attracting multinational companies to conduct clinical trials.

d) Infrastructure and environment

A highly functioning healthcare environment is crucial for supporting patient care and complex clinical trial designs. This includes advanced medical facilities, access to a diverse patient population, and supportive regulatory environments. Additionally, ease of doing business, such as simplified administrative processes and supportive government policies, further attracts multinational pharmaceutical companies to consider a country like Malaysia as a clinical trial destination.

Malaysia's top ranking highlights its strengths in these areas, particularly its large and genetically diverse population, which represents a third of global genomics. This diversity allows for the testing of different drug responses across populations, enhancing the quality of trial outcomes [34]. To further attract multinational pharmaceutical companies to invest and bring their clinical trials into Malaysia, we have developed strategies targeting key areas highlighted in Table 3 below.

> "It's very impressive that Malaysia has the well-structured ecosystem in clinical trial space to nicely support the fast development in recent years. Look forward to more success with this market and reaching new heights."
>
> **— Tia Chen**
> Senior Director, Country Head SMM, Malaysia and Singapore AstraZeneca

TABLE 3 Strategies for advancing clinical trials

Trial performance (speed and quality)	Expertise network	Regulatory Frameworks	Infrastructure and Environment
Set-up and activation timelines	Availability of labour force with relevant skills	Registration and approval policies	Healthcare environment
Ease of patient recruitment and retention, including diversity and rare disease recruitment	Quality and credibility of personnel	Clinical trial design innovation	Partnerships

Source: Clinicaltrials.gov, June 2024, IQVIA
White Paper: Attracting Investment in Clinical Development, IQVIA Analysis

3.1 Elevate trial performance

Speed and quality are the main drivers for country selection criteria for clinical trials. Multinational pharmaceutical companies face a highly competitive environment, in which speed is key to determining which innovation reaches the market first. Moreover, predictability of the forecasted timelines (e.g., start-up procedure length and complexity, and patient recruitment times) is critical for sponsors to plan for the clinical trial development and its subsequent phases within their budget allocations [34]. New technologies can provide solutions to optimize operations. For example, digital driven solutions to take existing EMR data and analyze it to provide insights on patients who may fit clinical trial inclusion criteria, while maintaining patient privacy. Digital tools enabling more efficient end-to-end submission system facilitates innovation by allowing for quicker iterations and responses to research findings, which is crucial for advancing medical research and delivering innovative treatments to patients sooner.

3.1.1 Accelerate trial approval pathways

In Malaysia, the ethics committee submission process varies based on the clinical trial site, whether it is a government health facility under the Ministry of Health (MOH), a university, or a private institution [35]. The submission might need to be tailored for different committee which could result in inconsistent timeline, or if the trial involves multiple sites from different sectors (government, private, academic), coordinating and synchronizing the timeline can be challenging, potentially leading to delays if one sector's review is slower.

In contrast, Singapore has adopted a Centralised Institutional Review Board CIRB model for multi-site trials, where a centralized IRB review is responsible for reviewing the trial on behalf of all participating sites [36]. Using a centralized review process for multicentre trials streamlines the approval process, saving both time and costs. It minimizes delays in participant enrolment especially in a global clinical trial where starting first means a higher chance of completing the country enrolment target as patient enrolment is usually competitive.

Malaysia has the framework to optimize and standardize ethics reviews and approvals which is what the Medical Research Ethics Committee's review and approval for MOH sites does. There is opportunity to further streamline this framework to include university and private hospitals to reduce the review and approval timelines to save time, costs, and resources of different ethics committee personnel. This will in turn save time from the investigators and multinational companies to prepare different submission applications to suit the different IRB/IEC requirements.

Here are some ways to accelerate the pathways:

- **Centralize submission system:** by establishing a centralized IRB or submission system that standardizes the review process, applying uniform submission standards and guidelines across all sectors.
- **Expedite review for low-risk trials:** by establishing criteria that quality certain types of studies for expedited review, this should free up resources for more complex review and help speed up the approval process for simpler studies. While this process is already in place, it is not consistently applied across all ethics committees, highlighting the need for standardized implementation.
- **Accelerate digital transformation and automation:** by adopting electronic document management systems, and automating routine tasks, the review and approval processes can be expedited. This would reduce paperwork, minimize human error, and enable real-time and audit tracking and updates on agreement status, enhancing transparency, and efficiency across all parties involved. This would work similarly to how medical device trials are being submitted and reviewed using Medcast (MDA). An up-to-date FAQs section or guidelines would also serve stakeholders in minimizing errors on submission. Ultimately, all these efforts would lead to a more efficient health authority approval pathway.

  Additionally, it is crucial to address the current challenges with the NMRR 2.0 system (a platform for all research submissions that requires Ethical Approval), while the current platform introduces new features, it has presented some challenges compared to the previous system. Users have reported that the current system can be more complex to navigate, which has occasionally led to delays and user frustration. This underscores the need for thoughtful selection and implementation of digital platforms to ensure they deliver on usability and performance. A well-designed system should streamline processes, be user-friendly, and meet the expectations of all stakeholders.
- **Increase regular training sessions and workshops:** by enhancing skills and ensuring compliance from each stakeholder can help maintain high standards of quality of submission.
- **Review and optimize MDA regulations for non-device trials:** The inclusion of MDA regulation in the clinical trial setup journey initially led to increased startup times. While MDA submissions are crucial for device-related trials, non-device clinical trials are also required to go through this process, which the industry views as an unnecessary step that adds time and cost. To optimize the approval pathway, the government could consider revising the MDA submission requirement for non-device trials, reducing the regulatory burden on these studies, and helping accelerate trial initiation. On regulatory acceleration, we should look at our neighbouring countries who are our competitors in clinical trial placements and ensure that the right regulation and policies remain effective.
- **Extend BLESS permit validity to 3 years:** Currently, clinical trials require an annual application for the BLESS permit, which involves repeated submissions and reviews, adding to administrative workload and potentially delaying trial continuity. Aligning the BLESS permit validity with the Clinical Trial Import License (CTIL) by extending it to a three-year term could streamline processes, allowing for uninterrupted trial operation and enabling resources to be better allocated to more critical aspects of clinical trial review and support.
- **Standardize and publicize regulatory meeting cadence:** a challenge in the clinical trial approval pathway is the lack of a standardized schedule for regulatory meetings, making it difficult for stakeholders to anticipate review timelines and plan accordingly. Establishing a public commitment to a regular cadence of regulatory meetings - such as monthly or quarterly sessions - would add predictability to the process. This transparency would enable clinical trial sponsors and researchers to better synchronize their application timelines and address any regulatory concerns promptly, ultimately improving trial approval efficiency.

3.1.2 Operationalize national databases

Electronic Medical Records (EMRs) are digital versions of patients' medical histories, designed to improve healthcare efficiency and accuracy by allowing electronic access and updates to patient information. EMRs have the potential to significantly enhance clinical trial outcomes by improving data accuracy, streamlining patient recruitment, and facilitating real-time monitoring of participant health metrics. This in turn translates to quality as data analysis and trending can be done in real-time and safety aspects can be reviewed by central monitoring teams. However, Malaysia still faces gaps in data capture and Health Information Systems (HIS) infrastructure implementation. Data capture methods are predominantly manual and conducted by tracing patients' clinical and treatment notes. 20% of the public hospitals utilizing EMR currently are using different systems, and the implementation varies within the hospital.

Additionally, the implementation of HIS has been hindered by inadequate integrated planning, with different hospitals using individual stand-alone systems and lack of uniform operational policies. [37]

A national strategy of real time data or registries to collect accurate epidemiological data to demonstrate therapeutic areas that may attract global trials to invest into setting up clinical sites in Malaysia. Singapore is a prime example of this having deployed and operationalized the National Registry of Disease Office (NROD) under the Ministry of Health (MOH) in 2001 governed by the National Registry of Diseases Act. NROD collect data on selected major disease and health conditions in Singapore and the data is made publicly available for external parties to understand the evolution of these diseases and conditions in Singapore.

South Korea is a notable example of an Asian country that has actively promoted the use of Electronic Medical Records (EMRs) to support clinical trials and healthcare research [38]. The South Korean government has implemented several initiatives to encourage EMR adoption and integration in healthcare settings, which in turn benefits clinical trial processes. One key initiative is the National Health Information System (NHIS), established to centralize and standardize health data including EMRs. This system supports interoperability between healthcare providers and research institutions, facilitating efficient data sharing for clinical trials. Additionally, the South Korean government has provided financial incentives and subsidies to hospitals and clinics to adopt EMRs, aiming to improve overall healthcare quality and research capabilities.

EMRs allows the opportunity for digital innovation, for example how to extract clinical trial data into the clinical trial management systems which can reduce the manual data entry that the research coordinator does now in the clinical setting when recording clinical trial data. This information is anonymized and quality is ensured as there is no transfer of patient information or identifiers which can happen in manual data handling.

In Australia, the use of EMR allowed for business continuity during the Covid-19 pandemic, as clinical research monitors could review hospital EMR data remotely to monitor clinical trial data for safety, quality, and compliance. In Malaysia, only University Malaya Medical Centre has the infrastructure and process to allow remote monitoring of clinical trials.

Here are some ways the government can support EMR integration:

- **Incentives for integration of automated EMR:** Invest in infrastructure to support the system or providing financial grants or tax incentives to healthcare providers for transitioning from manual data capture methos to automatic EMR systems.
- **Regular training programs:** Utilize lessons learnt from the existing hospitals with EMR for better planning and integration of EMR across the healthcare system. Additionally, it should educate hospital directors and regulators on the importance of monitoring and remote access to EMR and emphasizing how to provide the right level of access while adhering to Personal Data Protection Act (PDPA) regulations. By doing so, the program will foster a supportive environment for clinical trials through well-planned and integrated EMR systems.

- **Standards and regulatory frameworks for EMR interoperability**
  Establishing clear standards and regulatory frameworks for EMR interoperability is crucial for seamless data exchange between different healthcare systems. Governments can develop and enforce standardized protocols, such as Health Level Seven International (HL7), to ensure that EMR systems can communicate effectively with each other and with Clinical Trial Management Systems. These frameworks should also include guidelines for data security and privacy, ensuring that sensitive health information is protected. By promoting interoperability, governments can enhance the efficiency and quality of clinical trials and overall healthcare delivery.

3.2. Enrich expert network

Some multinational companies prioritize access to expertise over clinical trial speed, to build early relationships with local stakeholders (Key Opinion Leaders (KOLs) and influential Investigators) in target markets. The need for knowledge and access to these experts becomes increasingly important when entering new or lesser-known therapeutic areas. To increase Malaysia's attractiveness as a trial destination, policy makers must explore how they can inculcate an attractive local knowledge network for broad therapeutic areas. [34] In the oncology field, having experts familiar in the early development of a new compound can also mean better understanding of the drug mechanism, its benefits and handling of side effects. This improves the patient and healthcare provider's experience and helps them evaluate risk-benefit ratios more effectively.

3.2.1. Enhanced educational programs

To support the investigators and strengthen Malaysia's clinical trial sector, the government and universities can collaborate to develop enhanced educational programs tailored specifically for clinical research. These programs should focus on equipping researchers and clinical trial staff with essential skills and knowledge. By partnering with multinational pharmaceutical companies, Malaysia can offer specialized courses and certifications that align with global standards, ensuring a steady supply of trained professionals.
One effective strategy is to increase the number of placements available for specialist training. One of the recent positive developments in Malaysia is the implementation of parallel clinical oncology training programs with foreign universities whereby promising young clinical oncology trainees will be sent to these cancer centers of excellence abroad for 2 years of their total 4-year training program [28]. Such exposure especially during their early career paths, will provide them with invaluable exposure and subsequently inculcate their interest and passion in oncological research.

Additionally, Malaysia can standardize and expand its Good Clinical Practice (GCP) training across all institutions to ensure consistent and high-quality education. Aligning these programs with international standards will better prepare clinical trial professionals, like the structured career paths followed by aspiring Principal Investigators in countries like the United States. This includes stages such as residency, fellowship, transition to independent roles, and ultimately becoming a Principal Investigator.

- **Residency:** this initial stage involves completing a medical residency program after medical school, where individuals gain specialized training in a specific area of medicine. This provides them with the clinical expertise necessary to conduct research related to their field of specialization.
- **Fellowship:** this period allows aspiring PIs to develop deeper expertise and involves active participation in clinical trial projects, under the guidance of experienced mentors.
- **Transition:** during this phase, individuals transition from being a trainee to an independent role. They may start taking on more responsibilities in ongoing research projects or initiate smaller, pilot studies. This is a critical time for building a network, securing funding, and establishing a research portfolio.

- **Principal Investigator:** finally, after gaining sufficient experience, expertise, and recognition in their field, and demonstrating an ability to secure funding and lead research projects, individuals can assume the role of a principal investigator. This position involves designing and overseeing clinical trials, managing research teams, and being ultimately responsible for the conduct and integrity of the research. Principal investigators should also be afforded opportunities including exposure to leading FIH trials.

By fostering collaboration between the government, universities, and multinational pharmaceutical companies, Malaysia can build a robust clinical research workforce. This will not only enhance the country's attractiveness as a clinical trial destination but also improve the quality and efficiency of clinical trials, benefiting both patients and healthcare providers.

3.2.2 Attractive career pathways

Creating attractive career pathways in Malaysia's clinical trial environment can motivate more research professionals including principal investigators and study coordinators to enter and remain in the field of clinical trials. By clearly defining progression routes and offering opportunities for advancement and specialization, these pathways can enhance job satisfaction and retention, contributing to a more robust and sustainable workforce. Here are some ways to enhance these pathways:

- Recognition and award: While CRM already implements recognition programs, continued efforts to expand and promote such initiatives can further motivate young PIs.
- Partnership with hospitals or universities: facilitating partnerships with hospitals and universities can provide young PIs with access to a broader range of resources, including advanced technology, diverse patient populations, and additional funding source.

3.3 Enhance policies supporting clinical trials

Policymakers can catalyze clinical trial optimization and innovation by launching ambitious initiatives, accepting novel designs and use of real-world evidence. The industry welcomes innovative and bold initiatives for standardization in approval procedures and praise an open approach to co-creation. On top of that, policymakers will have to consider about how these implementations will best be operationalized and enforced. [34]

3.3.1 Establishment of clinical trial hub and support platform

Hong Kong has established the Greater Bay Area International Clinical Trial Institute (GBAICTI), which provides a one-stop clinical trial support platform, for research institutions and stakeholders, coordinating resources across both and private healthcare sectors, combining Hong Kong's international clinical trial experience with Shenzhen's extensive clinical networks [39]. To further support clinical trial, Hong Kong is planning to create the Cluster Clinical Research Support Office by the Hospital Authority (HA). This office will manage clinical trial networks and big data research across 43 public hospitals, facilitating and expediting the clinical trial process through various supportive measures.

CRM provides comprehensive support for clinical trials, including end-to-end services and integration with global clinical trial networks. Malaysia has a National Medical Research Register (NMRR) that serves as a platform for sharing information and progress on clinical trials and health-related research. However, unlike Hong Kong's initiative, Malaysia does not yet have a centralized institute that combines extensive clinical networks with big data research across numerous hospitals. A trial institute can streamline trial management and enhance infrastructure and talent development, making it easier for multinational pharmaceutical companies to conduct trials efficiently.

Additionally, there is an opportunity to expand the usage of the NMRR by integrating it with international platforms such as ClinicalTrials.gov. This integration would enhance global visibility and collaboration, making it easier for researchers and sponsors worldwide to access information about ongoing and upcoming trials in Malaysia. By tying NMRR into such global databases, Malaysia can position itself as a more attractive destination for clinical trials, leveraging increased transparency and accessibility to attract more international studies and funding.

3.3.2 Implementation of clinical trial innovation

Malaysia has shown a commitment to advancing clinical trials through adaptability and agility to pivot with the release of its Decentralized Clinical Trial (DCT) Guidance Document in July 2023. However, the country still faces challenges in fully implementing DCT infrastructure compared to other nations. For instance, Korea has made significant strides in this area since launching a comprehensive five-year plan in 2017 to strengthen its pharmaceutical industry. This initiative focused on building smart clinical trial platforms and an institutional framework to support efficient trials, utilizing Korea's advanced ICT infrastructure [40]. Companies like Marken Korea have played a pivotal role by offering Direct-To-Patient services and introducing the DCT Home HealthCare program, which significantly enhances participant convenience and trial efficiency.

In comparison, Malaysia's core DCT technology infrastructure remains underdeveloped. While the country has established guidelines, the actual implementation of the technology required to support decentralized trials lags South Korea's systems. Similarly, countries like Canada and Denmark have had more success in integrating DCTs, benefiting from a longer history of using digital health technologies and remote monitoring [41] [42] [43]. These countries have more mature frameworks that extensively prioritize patient-centric approaches, leveraging advanced digital tools for clinical trial execution.

In 2023-2024, Clinical Research Malaysia and Johnson & Johnson have jointly embarked on a Local Care Model Pilot that allows the clinical trial patient a choice to visit a qualified health care facility nearer to their homes for their clinical trial visit instead of having every visit at the clinical trial site.
In 2023, Johnson & Johnson included home health care visits in an oncology study that provided options for patients to be visited at home.

Although Malaysia is starting to incorporate similar technologies, it is still in the early stages of development and needs to enhance both its physical and digital infrastructure to match the levels seen in mature markets. This works as the logical next step to operationalize DCTs and would therefore effectively bring care closer to the patients. For example, patients should be able to visit nearby clinics to get samples taken for their trials rather than going to the primary center. In the patient-centric models shared among the three successful countries mentioned, the degree of implementation and technological maturity today still sets Malaysia behind its more advanced counterparts globally.

"From faster approvals to cutting-edge technology and streamlining digitalization, Malaysia is transforming the clinical research landscape. Our dedicated researchers and innovative approach are driving progress and bringing new treatments to patients."

— Sheikh Mohammad Norhafiz Abdul Aziz
Country Clinical Operations Lead, Roche

3.4 Enable clinical trials environment and infrastructure

Encouraging clinical trials is essential to tap into opportunities that can contribute to economic development and make an impact on patients' lives. Fostering a sustainable clinical trials ecosystem is a multi-stakeholder endeavour requiring collaboration between regulatory authorities, research communities, and funders to support and strengthen the capabilities to conduct clinical trials. Collaborative models such as clinical trial networks and public-private partnerships can pave the way for a more innovative and sustained approach to advancing clinical trials. Ensuring that clinical trial budgets remain fair and transparent is crucial for maintaining trust and integrity within the system. Additionally, public education should continue to elevate and expose the population to facts about clinical trials, building a well-informed community that supports and participates in these initiatives. By enabling a robust clinical trials environment and infrastructure, we can create a foundation for a sustainable future in medical research and patient care.

3.4.1 Clinical trials networks

Clinical Trial Networks (CTN) in which trialists work collaboratively enable multi-site, and high-quality clinical trials to be efficiently run. By working together and sharing existing infrastructure and resources, CTNs enable the ability to attract funding and undertake more influential studies. This leads to better data and real-world evidence generation that can be embedded in healthcare systems. The benefits of CTNs for stakeholders are well documented. In one study, the benefit to cost ratio of investigator-initiated clinical trials was 5.8:1; that is, for every USD 1 spent on trials, a return on investment of USD 5.80 is achieved, with similar economic benefits being reported internationally [44]. However, establishing a CTN can be complex with barriers such as cost, human capital, to name a few that increases the difficulty of this process.

In Australasia, a sizeable proportion of trials are conducted by geographically dispersed and multidisciplinary clinical researchers under the auspices of CTNs. In Australia, the Australian Clinical Trials Alliance (ACTA) is the national representing CTNs and guides effective implementation. To improve CTNs operations locally, ACTA conducted an extensive consultation process with CTNs operating across Australia and New Zealand to identify activities and attributes that enabled CTNs to operate successfully and developed a local roadmap for clinical trialists that are considering setting up or improving an existing CTN. Additionally, the potential of the PhAMA CRC as a foundational model could be considered, offering valuable insights and a practical starting point for CTNs aiming to optimize their frameworks and impact.

By better understanding the local context in which it operates; with the necessary government support to inculcate and operationalize CTNs locally, Malaysia has the potential to improve current evidence-based medicine and quality healthcare, as well as expand clinical trial activities, and tap into significant returns on investments. PhAMA CRC presents a promising starting point for establishing a robust CTN in Malaysia. By leveraging its existing infrastructure and expertise, PhAMA CRC can facilitate collaboration among stakeholders, streamline processes, and attract funding. This initiative can enhance the generation of high-quality data and real-world evidence, integrating evidence-based practices into Malaysia's healthcare system. With strategic support, PhAMA CRC can position Malaysia as a key player in global clinical research.

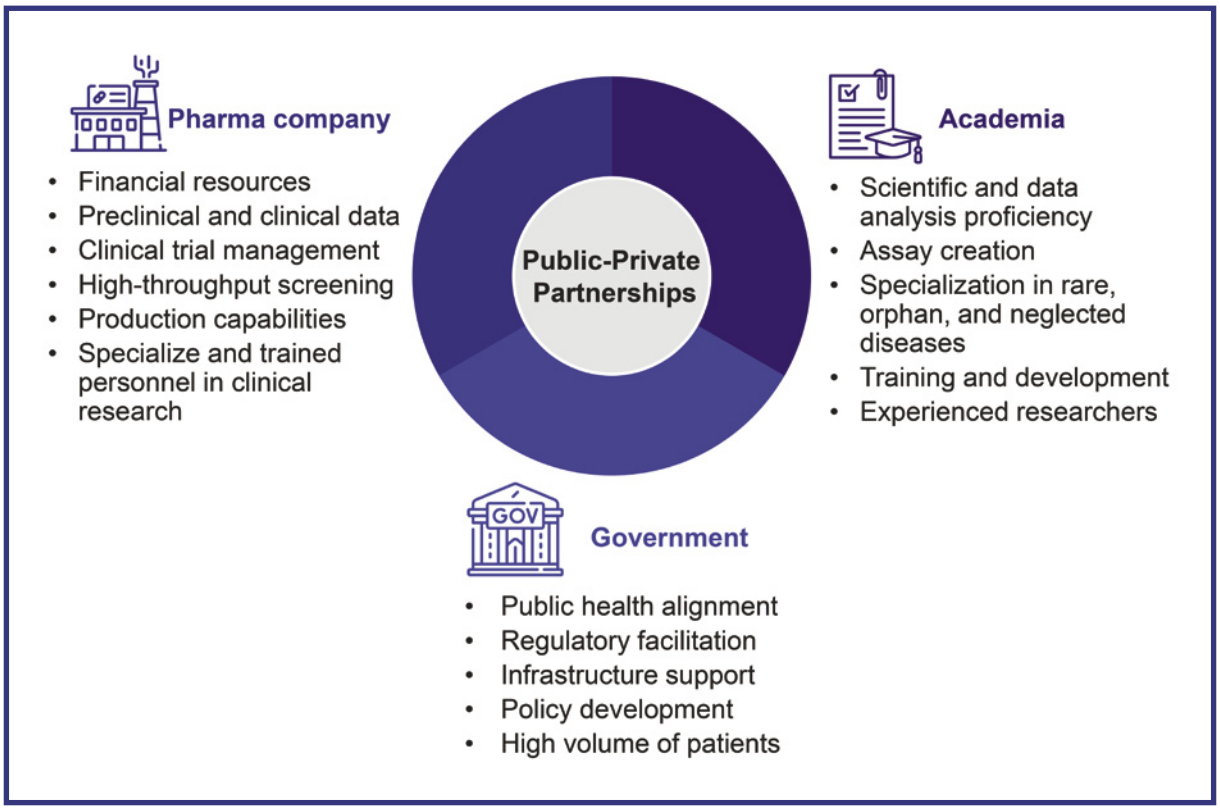
4.2. Public-private partnerships

In the past, efforts have been made to bridge the gap between public and private partnerships to encourage clinical trial involvement of experienced investigators who have left the government sector and moved to the private sector. However, challenges deter this from being fully adopted such as bureaucracies, governance and lack of clear process and policies. To address the challenges of a shortage in both the quality and number of well-equipped clinical trial sites, fostering public-private partnerships (PPPs) can be an effective strategy. Healthcare PPPs offer governments the opportunity to leverage private sector expertise and resources, to enable investment in large-scale projects that advance the nation's public health goals such as improving the quality-of-service delivery e.g., reduced time and expanding access to care.

Infrastructure-based model PPP is the most common type of engagement used in bridging the gap that exists within the clinical trial industry. This model has been adopted in various countries for value creation in the clinical trial industry for example Johns Hopkins University has collaborated with LabCorp, one of the largest clinical laboratory networks in the world to enhance diagnostics capabilities and support clinical trial projects. This partnership has been pivotal in advancing personalized medicine and improving diagnostic accuracy through comprehensive laboratory testing and data analysis [45].

Malaysia is no stranger to healthcare PPPs especially in clinical trial as Clinical Research Malaysia (CRM) has initiated collaboration with private entities to increase the country's capabilities in conducting clinical trials [8]. For instance, the Ministry of Health initiated a public-private partnership in oncology, where a pilot project was launched at three public hospitals, allowing private sector oncologists to collaborate with clinical specialists such as haematologists, surgeons, and gynae-oncologists in conducting industry-sponsored research. This initiative aims to enhance the uptake of oncology clinical trials in Malaysia by leveraging the capabilities and resources of both sectors. There still exists room of improvement in terms of PPPs in Malaysia to streamline processes, reduce costs, and enhance the overall efficiency of clinical trial efforts in the country. There is also opportunity to enhance the referral network of clinical trials from public networks and from public to private, so patients have options and choices, but the process is challenging and deters referrals unless it is driven by the patient or a dedicated investigator.

FIGURE 10 Illustrates the contribution of each stakeholder in PPP, which can serve as a model for further expansion in Malaysia's clinical trial efforts



IMPERATIVES FOR GOVERNMENT

The government plays a crucial role in facilitating a clinical trial ecosystem and trial success by establishing initiatives and policies that strengthens collaboration among multinationals, research entities, and agencies and enhances the research domain, creating a conducive environment for clinical advancements.
Securing long-term commitment from policymakers for regulatory reforms and strengthening local expertise and partnerships will drive growth in Malaysia's clinical trial ecosystem, boosting early-phase work, larger enrollments, and economic value, positioning the country as a competitive global trial destination.

Key recommendations:

i) **Trial performance**

- Accelerate regulatory and ethics approval pathway to reduce administrative burden and minimize delays by standardizing reviews across all sites.
- Operationalize national databases to provide sponsors and sites transparency and easier access to patient and disease information.

ii) **Expertise network**

- Enhanced educational programs between academia, industry, and healthcare institution, including access to scholarships, training program, and educational seminars or workshops to continually enrich the quality and credibility of personnel involved in clinical trials. Protected time for investigators recommended to encourage investigators to balance clinical and research work.
- Attractive career pathways by codifying clear professional advanced and rewards to attract and retain a solid local network of experts and ensure industry access to a sufficiently skilled workforce.

iii) **Regulatory framework**

- Establish a clinical trial hub through regulatory policies that streamline trial operations and ensure robust infrastructure in enhancing overall trial management.
- Strengthen regulatory support for the implementation of clinical trial innovation to accelerate innovation and infrastructure to support decentralized clinical trials.

iv) **Clinical trials environment and infrastructure**

- Clinical trial networks to share existing resources, expand clinical trial activities, attract funding, and undertake more influential studies.
- Public private partnerships to better leverage expertise and resources of the private and public sectors and enable broad investments in more large-scale research.

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Glossary

ABBREVIATION	DEFINITION
ACTA	Australian Clinical Trials Alliance
APAC	Asia-Pacific
CAGR	Compound Annual Growth Rate
CoE	Centre of Excellence
CRA	Clinical Research Associates
CRC	Clinical Research Centre
CRM	Clinical Research Malaysia
CRO	Clinical Research Organization
CTA	Clinical Trial Agreement
CTMS	Clinical Trial Management Systems
CTN	Clinical Trial Notification
CUHK	Chinese University of Hong Kong
DCA	Drug Control Authority
DALY	Disability-Adjusted Life Year
DCT	Decentralized Clinical Trial
EMR	Electronic Medical Records
FDA	Food and Drug Administration
FIH	First-in-Human
GBAICTI	Greater Bay Area International Clinical Trial Institute
GCP	Good Clinical Practice
GDP	Gross Domestic Product
HA	Health Authority
HCTM (formerly HUKM)	Hospital Canselor Tuanku Muhriz (formerly known as Hospital Universiti Kebangsaan Malaysia)
HIS	Health Information Systems
HUSM	Hospital Universiti Sains Malaysia
ICH E6	International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
IND	Investigational New Drug
IRB	Institutional Review Boards
SR	Industry-Sponsored Clinical Research

ABBREVIATION	DEFINITION
IT	Information Technology
KOL	Key Opinion Leaders
MIDA	Malaysian Investment Development Authority
MNC	Multinational Corporation
MOH	Ministry of Health
MoU	Memorandum of Understanding
MP1CTG	Malaysian Phase 1 Clinical Trial Guidelines
MREC	Medical Research and Ethics Committee
MRI	Magnetic Resonance Imaging
NED	No Evidence of Disease
NGO	Non-profit organization
NHIS	National Health Information System
NIMP	National Industrial Master Plan
NIP	New Investment Policy
NKEA	Healthcare National Key Economic Area
NMRR	National Medical Research Register
NPRA	National Pharmaceutical Regulatory Agency
NROD	National Registry of Disease Office
P1RP	Phase I Realization Project
PhAMA	Pharmaceutical Association of Malaysia
PI	Principal Investigator
PPP	Public-private partnership
R&D	Research and Development
REC	Research Ethics Committees
SDG	Sustainable Development Goals
SGH	Sarawak General Hospital
SRP	Scientific Review Panel
TNBC	Triple-Negative Breast Cancer
UMMC	University Malaya Medical Centre
UN	United Nations

About the Pharmaceutical Association of Malaysia (PhAMA)

Established 53 years ago, the Pharmaceutical Association of Malaysia (PhAMA) is a non-profit trade organization that represents local and multinational companies involved in the importation and distribution of innovative pharmaceutical products in Malaysia.

The association has come long way since its inception in 1972. Initially registered as the Malaysian Pharmaceutical Trade and Manufacturers Association, PhAMA today is recognised as the backbone of the innovative medicines industry in the country. Over the decades, PhAMA has established a high reputation of professionalism and integrity in the fields of science, technology, innovation, and ethical marketing.

Today, PhAMA continues to play a pivotal role in advocating for and promoting the development of the pharmaceutical industry in Malaysia. The organisation collaborates with multiple stakeholders, including government bodies, healthcare professionals, and multinational companies, patient groups and the larger healthcare eco-system, leveraging on the expertise and experience of global and local partners and collaborators to co-create impact for individuals and communities.

At the core of its operations, PhAMA acts as a conduit for the pharmaceutical industry in establishing regulatory frameworks, facilitating strategic collaborations and driving national policy. In the next decade, PhAMA is poised to play an increasingly bigger role in expanding the talent pool in the biopharmaceutical and clinical research sectors, contributing towards the creation of a knowledge-based economy in Malaysia.

PhAMA Members

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