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Driving Clinical Research for the Nation

RESEARCH PERSONALITY
Dato' Dr. Fam Tem Lom

FEATURED SITE
CRC Hospital Miri

SPECIAL COVERAGE
A Unique Model to Accelerate Industry-sponsored Research in Malaysia

ABOUT CLINICAL RESEARCH MALAYSIA

Clinical Research Malaysia (CRM) exists to advance global health solutions for a brighter, more hopeful future for the people by providing speedy and reliable end-to-end clinical research support for quality studies. As these studies unfold, we work together with our partners to create an impetus in delivering better treatment to our end consumers, while at the same time creating high-skilled job opportunities.

The strength of our operation lies in our innate understanding of the local clinical research landscape and implementation of international standards. This, when considered in parallel to the fundamental backing of the government ministries, provides us with an incomparable advantage, as we work hand-in-hand with our partners from the nascent stages of development to materialisation of the end product.

In the journey towards a brighter and better future, we facilitate the entry of industry-sponsored research into Malaysia, working closely with the government and relevant authorities to ensure that all regulations and best practices are met.

In CRM, we credit the outstanding performance to the team we have anchored from within our organisation. Their endless pursuit of innovation and continuous improvement have propelled CRM forward to optimise the opportunities that come our way. In tandem with our passion for the clinical research landscape, we ensure core values of transparency, honesty, accountability and trustworthiness resonate throughout CRM. These qualities are also cascaded to our principal investigators and Study Coordinators, who act as the catalysts of the clinical research process.

As CRM vouches for an aspiring future in the clinical research industry, we have implemented mechanisms to expand hospital capacity for clinical trials and tests. This is possible by tapping into our vast talent pool consisting of principal investigators and medical assistants.

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FROM THE CEO's DESK

The global clinical trials market size was estimated at USD44.2 billion in 2018 and is anticipated to expand at a CAGR of 5.7% over the forecast period. Clinical trials bring various socioeconomic benefits to the country and its people. However, it is unfortunate that only RM 128 million worth of clinical trial studies was brought into the country, contributing to only 0.07% of the market share.

Through the establishment of CRM and its close collaboration between CRC, the various ethics committees and the regulators, the country managed to reduced its start-up timeline from 306 days in 2015 to 150 days in 2018. Earlier this year, CRM was also successful in obtaining the ISO 9001:2015 accreditation, a feat we are very proud of as being the only research management company in the region with this accreditation.

Yet, we cannot be complacent with our achievements. There have been several major challenges that Malaysia has to overcome in order to be competitive in the global clinical research field and to attract more sponsored research into the country. In order to stay competitive within the region, issues with regards to GMP PIC/S, electronic medical records and comprehensive/updated registries needs to be addressed. We also need to recognise sponsored research as a foreign direct investment as it creates new job opportunities, provides treatment to our patients at no cost and at the same time develops our clinicians to be world class investigators.

With this in mind, CRM has been engaging with the relevant stakeholders and policy makers to ensure these challenges are acknowledged and addressed, especially in being actively involved in the Technical Working Group of the Rancangan Malaysia ke-12 (2021-2025). It is our hope that clinical research is recognized as an industry in Malaysia that contributes significantly to the people and the country.

Dr. Akhmal Yusof
CEO, Clinical Research Malaysia

Contents

CRM's New Office Launched by Minister of Health, YB Datuk Seri Dr Dzulkefly Ahmad

KUALA LUMPUR, 26 February – CRM's new office was launched by the Minister of Health Malaysia, YB Datuk Seri Dr Dzulkefly Ahmad. It was witnessed by members of CRM's Board of Directors, CRM's Senior Leadership Team and member of the press. The new office is located at Menara SuezCap, KL Gateway. CRM will continue to support and grow clinical research in the country from its new office.

CRM Collaborates with Two Prominent Singapore Organisations to Advance Clinical Research

KUALA LUMPUR, 26 February – Clinical Research Malaysia (CRM) inked two Memorandum of Understanding (MoUs) with two prominent Singapore organizations in the field of clinical research. This further paves the way for better Malaysia–Singapore collaborations in advancing drug development and research capabilities between both countries. The MoU with the National University Hospital (Singapore) Pte Ltd (NUH) spells out support in the areas of clinical trial promotion, business development, networking opportunities, clinical trial operations, training as well as in feasibility assessments. The initial focus of the collaboration will be in oncology clinical trials and masterclasses conducted by the National University Cancer Institute, Singapore (NCIS), which is part of the NUHS.

CytoMed Therapeutics is a spinoff company from Singapore's Agency for Science, Technology and Research (A*Star) and has been developing treatments to treat a wide range of cancers using the patient's or donor's immune cells. CytoMed Therapeutics will be partnering with the IMR, which is being represented in this MOU by CRM to conduct an immunotherapeutic preclinical study initially. As the project progresses further, this will open up possibilities for future studies that go beyond the preclinical stage into translational studies and clinical trials.

Grant Writing Workshop by Dr. Albiruni Razak

KUALA LUMPUR, 4 March – CRM organized a 2-Day Grant Writing Workshop which was conducted by Dr Albiruni Razak. The workshop was attended by 42 participants including specialists, research scientists and medical officers from various institutions and hospitals. Dr Albiruni is an Assistant Professor at the University of Toronto and Medical Oncologist at the Princess Margaret Cancer Centre in Toronto. The paticipants learnt the skills of grantsmanship in order for their grant application to have a higher chance of successful funding at the international level.

NHAM-CRM Research Track 2019

KUALA LUMPUR, 14 April 2019 – This is CRM's 3rd year collaborating with National Heart Association of Malaysia (NHAM) for the NHAM-CRM Research Track 2019 held at the Kuala Lumpur Convention Centre. Prominent speakers in the field of cardiology such as Prof Chim Lang from the University of Dundee as well as other local experts in this field presented their latest discoveries. The NHAM-CRM Research track provides a platform for researchers and scientist to gained insightful advice from clinicians in order for their research findings to be more clinically relevant and have a better commercialization value. This year, we received 22 abstracts submitted were the basic science/translational research and biomedical/public health/clinical categories.

Completing the Clinical Research Ecosystem

KUALA LUMPUR, 24 April – The biannual CRM Industry Dialogue provides an avenue for Pharmaceutical companies (sponsors) and CROs to directly convey any issues, suggestions or opinions that they may have to CRM. By bringing together these industry players, CRM uses this platform to connect with them and provide upates on its current and future activities. Speakers from the clinical research industry, regulators and ethics committee presented in this event. This includes Ms. Yip Su Lyn (Country Manager, Novotech), Dr. Zaril Harza bin Zakaria (Deputy Director, Centre for Investigational New Product, NPRA) and Dr. Hjh Salina Abdul Aziz (Chairperson, MREC).

Insightful Investigator Dialogue for 2019

KUALA LUMPUR, 25 April – CRM Investigator Dialogue 2019, a platform to discuss relevant matters in conducting Sponsored Research. A total of 36 investigators from MOH hospitals and university hospitals attended the event.

Network of Ethical Review Committees in Malaysia (NERCIM) 2019/1

KUALA LUMPUR, 17 April – Medical Research Ethics Committee (MREC) & CRM co-organized the first for this year's Network of Ethical Review Committees in Malaysia (NERCIM) in Menara SuezCap. It was attended by representatives from IRBs in Malaysia with guest speakers Ms Lyca Manembu, Manager (Regulatory and Start-Up), IQVIA, representative from the Health Informatics Centre, Ministry of Health Malaysia and Mr Nicholas Leow Chun Wei, NPRA. NERCIM is organized twice a year to harmonize the review process of all IRBs in Malaysia.

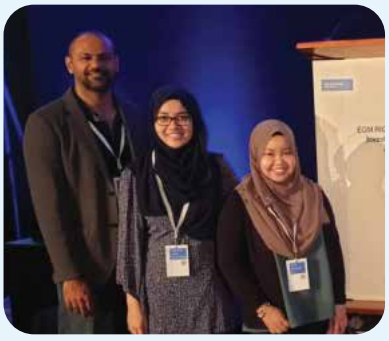
Double Joy for Hospital Miri on Patient Recruitment

KUALA LUMPUR, 9 May – Congratulations to Dr. Fam Tem Lom and Dr. Louise Ngu, and their study team for being the first in Malaysia to recruit patients for Influenza A (on 15 March) & Peads RSV (on 7 May) study respectively. CRM team is truly proud of these achievements and hope for more great news from Hospital Miri.

Congratulations Dr. Chan Lee Gaik & Hospital Umum Sarawak study team

KUALA LUMPUR, 9 May – Congratulations to Dr. Chan Lee Gaik and Hospital Umum Sarawak study team for recruiting the first subject in Malaysia for Peads Influenza study on 13 March and achieving extended recruitment target on 30 April.

Congratulations Oncology Department in HKL!



KUALA LUMPUR, 18 June – Congratulations! to Dr. Malwinder Singh Sandhu & his team over in Hospital Kuala Lumpur as the first recruiter globally for a breast cancer study on February 2019. Thank you team for making Malaysia #1!

Research Proposal Writing Workshop by Dr Masliza Mahmod

KUALA LUMPUR, 19 June – CRM invited Dr Masliza Mahmod to hold a 2-Day Research Proposal Writing Workshop in Kuala Lumpur. 35 participants which include researchers, specialists and pharmacists from various institutions and hospitals attended this event. Guest speakers Assoc Prof Dr Ivy Chung, Deputy Dean of Research Cluster and Dr Mahmoud Danaee, Visiting Senior Research Fellow, Dept. of Social & Preventive Medicine, Faculty of Medicine both from University of Malaya were also present to speak on their field of expertise.

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Dato' Dr FAM TEM LOM

Consultant Physician – Internal medicine
Fellow Royal College of Physician of Ireland ,
Fellow Royal College of Physician Of Glasgow
Head of Infection Control, Miri Hospital
Certified Occupational Health Doctor, Malaysia

Dato' Dr. Fam Tem Lom was born and raised in a small town in Sarawak called Kampung Beratok. His father is a smallholder planting pepper plants and rubber trees. Dato' Dr. Fam is the 9th of 15 siblings and they live in a simple house with earthen floor where he shared a room with four of his siblings until he left for university.

In those days, he and his siblings wake up early to help tap rubber and tend to pepper plants and then helps out again after school and completing their homework.

Having graduated from UNIMAS in 2002, Dato' Dr. Fam went on to serve as a Houseman and then as Medical Officer and Clinical Specialist at Sarawak General Hospital from 2002 until 2010. He obtained the MRCPI in 2007 and FRCPI and FRCP (Glasgow) in 2015. It was in 2010 that he got posted to Miri General Hospital where he stayed until today.
In 2016, Dato' Dr. Fam was bestowed the DIMP by his Royal Highness Sultan Haji Ahmad Shah Al-Musta'in Billah ibni Almarhum Sultan Abu Bakar Ri'ayatuddin Al-Mu'adzam Shah which carry the title Dato'. He is married to Datin Dr. Doreen Chan Chu Ching and has three children.

Can you tell us when and how did you first got involved in clinical research?

I first got involved in Industry Sponsored Research in 2014 when the Clinical Research Centre (CRC) at Hospital Miri was in its nascent stage. It was a very difficult time for research, adding to the fact that I was very new to research and had doubts regarding my ability as a researcher.

Fortunately, under the mentorship of Datuk Prof. Dr Sim Kui Hian and support from the Hospital Director, Dr. Jack Wong Siew Yu, and the then Head of CRC, Dr. Doris Evelyn Jong Yah Hui, I began involved in clinical research. Clinical Research Malaysia (CRM) headed by Dr. Akhmal Yusof and its Study Coordinator, Jennifer Elia Anak Jon was also very instrumental in my journey in clinical research.

The study went through without a hitch, much to my relief. From there I gained confidence in conducting subsequent studies.

How has a clinical trial changed your practice and management of patient care?

I had my doubts of certain protocols and efficacy of treatments. I would say clinical trials is an extension of evidence-based medicine. Some of these doubts were dispelled and some were substantiated.

Of course I tweaked my treatment accordingly for the benefit of the patients. I like to qualify this statement by saying only when the completed trials have proven unequivocally that the treatment needed changing.

I find that I am now more discipline and accountable in documenting patients' treatments. I also come to understand why certain protocols were necessary for certain treatments.
Overall, I felt I have become more efficient and more confident in my core clinical work.

What are the main challenges you encounter when conducting clinical trials and how do you overcome them?

I think the main challenge of any researcher is funding. If you do not have enough money, no matter how good and relevant your research is, it is not going to take off.

Looking for funding is an ongoing process. It helps that we have established our name and reputation as a credible research centre so people or agencies are willing to fund us.

I am grateful for our study coordinators Salina Lisang, Wan Ainor Syahdah Binti Wan Hassan, Sylvia anak Stephen Bejit and Tan Sia Hong for their efforts in this aspect.

Of course there is the time challenge so our trials will not be protracted and dragged on. We continuously monitor and have in place a well-planned research structure and strict protocols that we adhered to.

What is your motivation behind conducting clinical trials?

We dare to dream big. We are a small hospital, one of the many hospitals in the whole of Malaysia. We want to play our part to make Malaysia's healthcare research standard and quality as one of the best in the region, and if possible, on par with Singapore.

Of course it is not going to be an immediate achievement. We have to achieve this in stages. For example, being best in the northern zone of Sarawak and then best in Sarawak, and moving up thereafter.

What one word best describes your career as a clinical researcher / investigator? Why?

Gratitude

I am grateful to be given a chance to helm so many important research and to have an efficient team who are motivated and work very hard to achieve the target.I am also grateful to my superiors who trusted in me and gave me the chance to take up important tasks even though there are many whom I felt were also qualified and more senior. Not forgetting Clinical Research Malaysia and the local Clinical Research Centre for their support in the conduct of clinical research.

Dato' Dr Fam with his clinical trial team in Hospital Miri.

I am also indebted to my wife Datin Dr. Doreen Chan Chu Ching who is always very supportive of my endeavours.

In the field of clinical research, where do you wish to see Malaysia in the next 10 years?

My dream is for Malaysia to be one of the best in the region. It is not going to be easy. We need to start our researchers young, nurture them and give them ample opportunities to grow. I believe that government public hospitals is the ideal place to do clinical trials.

Having said that, it is also important to ensure that Study Coordinators are paid well and given incentives as they play a very vital part in supporting clinical research.

More research in herbs are needed to assess their effectiveness in the medical field as they may have the potential to be developed into novel therapies.

What changes would you like to see being made by the policy makers to create a more conducive ecosystem for the conduct of clinical trials in Malaysia?

I hope that the policy makers can make clinical research a top priority either above clinical services or to give it the same priority. That should translate into more funding every year.

It is equally important to have more incentives for the medical officers to do research. For example, setting up a career pathway for those interested or have an aptitude for research to become medical clinical researchers. Additionally, housemanship for those with medical degrees can be waived and they can be absorbed directly to become clinical researchers.

This may sound drastic but with the current scenario where there are so many medical graduates and our service are unable to absorb a significant number of them and not all of them may be interested in doing clinical work, this may be something that the policy makers may want to consider. Thus the need to have/provide an alternative career pathway for medical graduates.

A Unique Model to Accelerate Industry-sponsored Research in Malaysia – Journal for Clinical Studies

Article published on the January 2019 Issue of the Journal for Clinical Studies.

The influx of industry-sponsored research (ISR) into the Asia Pacific region is continually growing due to the rising costs and complicated processes involved in drug development. Several countries within the region such as Singapore and, more notably, South Korea, have taken the initiative to develop and further strengthen their place as preferred destinations to conduct clinical trials. One such initiative is the establishment of specific entities that focus on nurturing and expanding the existing clinical trial ecosystem within the individual countries. With over 20 years of experience in conducting late-phase trials, the Malaysian government is no exception.

In the last six years, Malaysia has been steadily building a comprehensive and supportive clinical research ecosystem within the country. This includes the creation of Clinical Research Malaysia (CRM), a non-profit company wholly owned by the Ministry of Health (MOH).1 This review will present CRM as a unique business model, established to create a thriving and comprehensive ecosystem for ISRs in Malaysia and how this business model may be relevant and replicated in Asian countries that are looking to focus on attracting ISRs.

Clinical Research Malaysia – Addressing the Need for a Unique Business Model

Previously, sponsors and CROs have found it challenging in understanding the requirements, processes and systems involved in conducting ISRs in Malaysia. As a result, the time taken for them to bring in a clinical trial would have been prolonged. As Malaysia gears itself to increase the volume of ISRs into the country, the government is continually taking steps to develop its clinical research ecosystem. To this end, developing mechanisms to ensure that these studies are performed and managed efficiently from its inception has been a main focus. One such example is a "centralised support service"[1] that should facilitate the business and administrative aspects of clinical trials.[2]

Tang et al. determined that a focused research infrastructure is able to facilitate rapid development of trials (faster trial progress from institutional review board (IRE) approval to activation by 1.1 months and from activation to first enrolment by 0.3 months in ISRs) as well increased patient accrual rates.[3] Though the infrastructure studied focuses on oncology trials, some of its components such as a "capitalist" research model, enrolling patients from early-phase trials into subsequent later-phase trials, parallel processing for trial approval and a decentralised staffing model can be extended to government and research institutions to cultivate a thriving clinical trial ecosystem.

In the Asia Pacific region, other countries have also established similar entities to further advance their clinical research industry. Two examples are the formation of the South Korea National Enterprise for Clinical Trials (KoNECT) and Singapore Clinical Research Institute (SCRI). KoNECT was established to nurture the country's clinical trial infrastructure and capabilities[4] while SCRI is dedicated to enhancing the standards of clinical research capabilities in Singapore.

Creation of CRM

Acknowledging the significant growth of the drug development industry, the Malaysian government ensured the National Key Economic Area (NKEA) encompassing the healthcare industry included the creation of a supportive ecosystem to grow clinical research.1 Its focus is to allow for the conduct of more efficient and higher quality trials by increasing the number of clinical research centres, developing a larger pool of certified investigators and improving approval timelines.[5] Therefore, CRM was established in 2012 to effectively increase the speed, reliability and delivery of outcomes for all stakeholders involved in clinical research. Its vision is to highlight

Malaysia as a preferred global destination for clinical research by improving the local ecosystem to support the growth of ISRs within the country.[1] As a non-profit company that is wholly owned by the Malaysian MOH, it is governed by a board of directors that include the Minister and Secretary General of the MOH, the Director of the National Clinical Research Centres and representatives from the Pharmaceutical Association of Malaysia and university hospitals. The management team of CRM follows that of a corporate entity headed by a CEO and senior leadership team comprising finance, human resources, business development and clinical operations.

Challenges Within the Malaysian Clinical Trial Ecosystem Prior to CRM

Before the establishment of CRM, the country faced several challenges that dampened the conduct of ISRs. These included long-drawn-out hiring and asset acquisition processes that involved complicated and fractionated government bureaucracy, poor transparency of funds management and a lack of activities to increase the number of talented and trained human resource, as well as adequately set-up trial investigation sites. There was also no clear research pathway to develop the potential interests of existing investigators and support staff, and a need to ensure that the pool of experienced principal investigators (PIs) was maintained through proper succession plans. Further, there was a need to manage the whole national clinical research ecosystem under one centralised body. This entails collaborating with various stakeholders within the clinical research ecosystem, such as sponsors and contract research organisations (CROs), private and public doctors from universities, health clinics and hospitals, as well as the regulatory agencies and ethics committees, under a single point of contact to facilitate the processes of end-to-end activities involved in conducting ISRs.[1]

CRM as a Unique Working Model

The detailed objectives of CRM as discussed in a prior article[1] are to locally improve capabilities at trial sites and of human resource required to run trials which conforms to international quality and standards, establishing high quality feasibility assessments and investigator selection mechanisms and ensuring speedy and transparent administrative processes, especially in the management of the clinical trial budget.

CRM is also tasked to initiate and grow collaborations locally and internationally to bring in investments by global pharmaceutical and CRO companies and address the lack of awareness of and interest in clinical research among the healthcare fraternity and the public.

As a whole, the objectives of CRM are to leverage Malaysia's distinct advantages such as its diverse and large clinical trial-na'ive population, its low clinical trial density,[6] low health costs6 and competitive approval timelines compared to its counterparts in Asia. Part of its objectives is to also develop the existing infrastructure for the country's clinical research centre (CRC) network, which is an extensive network of research centres, housed within various MOH hospitals.[7]

Strategies

There are five pillars that constitute CRM's strategies toward accomplishing its objectives. These are to grow the numbers of PIs and sites conducting ISRs, to increase the volume of ISRs, collaborate with stakeholders, create awareness of CRM and develop human capital. Overall, the strategies allow CRM to centralise the management and optimise and mobilise resources quickly and efficiently.

Being an entity under the MOH facilitates CRM's initiatives and activities with private healthcare facilities, regulatory agencies such as the National Pharmaceutical Regulatory Agency (NPRA), which is its main stakeholder, and ethics committees. It also gives CRM access to the large CRC networks and its investigator database, the Medical Research Ethics Committee (MREC), the Medical Device Authority (MDA) and various other MOH components. Through its government affiliations, CRM is able to work with university hospitals and their individual institutional review boards (IRBs), the Malaysian Investment Development Authority (MIDA) and other important government agencies that have roles in developing a healthy clinical trial ecosystem within the country.

Complimentary Feasibility Studies

In an effort to attract global sponsors and CROs into Malaysia, CRM offers a range of services to support and facilitate their needs in conducting ISRs. One of the key core services that CRM offers is providing feasibility studies and investigator matching at no cost to sponsors and CROs. A clinical trial feasibility is a process of evaluating the possibility of conducting a particular clinical trial in a particular geographical region with an objective of running a trial at an optimum timeline, cost and patient accrual rates. The centralised feasibility service by CRM functions as a single point of contact for sponsors and CROs. It capitalises on a comprehensive updated internal database of investigators, enables outreach to a wider range of investigators and sites, and leads to streamlined communications, which reduces delay and confusion on the ground.

Prior to having a centralised feasibility management service in Malaysia, sponsors and CROs had to conduct feasibility assessments individually by relying on their own internal databases, which are based on their company's experiences with previous feasibility studies.[8] Additionally, due to the dynamic nature of Malaysia's research ecosystem, these individual databases have led to inaccuracies, which have misguided and delayed feasibility approaches. Examples of the dynamic changes are movements (e.g. promotions, transfers or retirements) of

investigators within the healthcare setting, changes in regulatory environment, site staffing or person in charge, and resources leading to change in site capabilities.

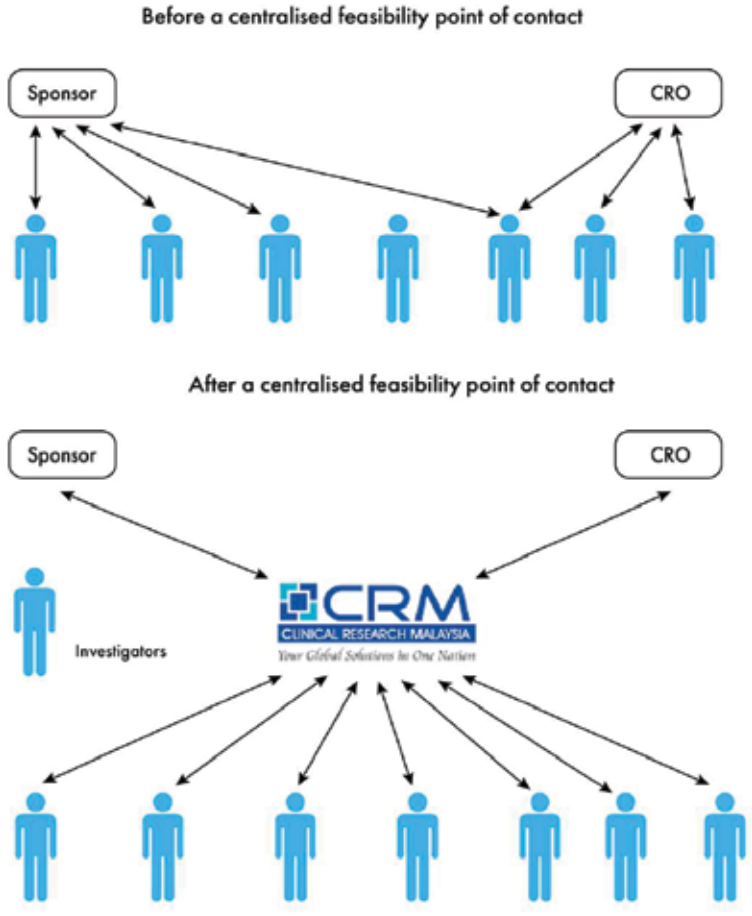

Figure 1.

A centralised feasibility service, on the other hand, allows for a single point of contact that capitalises on CRM presence in all 33 major clinical research centres nationwide, which enables it to have a comprehensive database that is frequently updated, which ultimately reduces delay for ISRs initiation (Figure 1).

On a nationwide perspective, a centrally managed feasibility structure is an attractive alternative to sponsors and CROs looking to enhance efficiency and width of a feasibility outreach, avoid redundant processes and promote a more accurate assessment of Malaysia's capabilities.

Consultation and Management of Clinical Trial Budget

CRM is authorised by the Malaysian government to act as a trustee in managing the budgets of clinical trials conducted in the country by receiving and executing its disbursement. It ensures that payments are made to the relevant parties involved in the conduct of clinical trials and that they are made in a fair and transparent manner. The majority of investigators conducting clinical trials are in the government sector, and according to the General Orders of the Malaysian Government,[9] investigators who are government officers shall not receive money paid directly to them (from sponsors/CROs) derived from their clinical trial activities. In light of this, CRM legitimises the transfer of the trial funds by managing the trial budget and channelling the investigators' fees to the relevant investigators.

Placement of Study Coordinators

CRM recruits and provides training for its study coordinators (SCs) who are then placed at trial sites nationwide to assist investigators with ISRs. At the start of 2018, there were about 110 study coordinators. To ensure that these SCs continuously maintain a high standard of professionalism, frequent trainings related to clinical research such as Good Clinical Practice (GCP) refresher courses, protocol deviation workshops and recruitment trainings are conducted for them.

Review of Clinical Trial Agreement and Non-disclosure Agreement

CRM also assists investigators, sponsors and CROs by reviewing and advising on clinical trial agreements (CTAs) and non-disclosure agreements (NDAs). CRM's experienced legal officers ensure that all agreements made in relation to the conduct of clinical trials in Malaysia comply with the applicable laws, regulations and guidelines of the Malaysian government. This has significantly reduced the duration of the CTA reviewing process from three months to 14 days.[1]

Outcomes

The outcomes of bringing together the various touch points involved in ISRs speak to the success of CRM's unique model. In financial terms, the

investment value cumulatively from CRM's inception in 2012 to 2017 has reached more than RM240 million, which is 42% of its 2020 target.

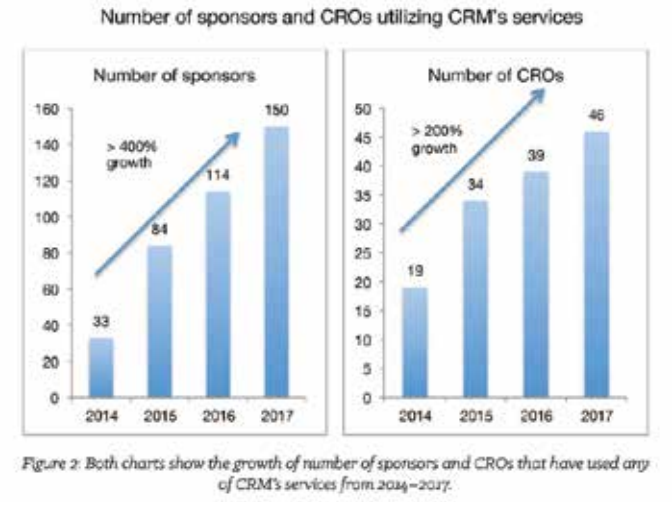

Figure 2: Both charts show the growth of number of sponsors and CROs that have used any of CRM's services from 2014–2017.

Between 2014 and 2017, there was more than 400% growth in sponsors and more than 200% growth in CROs that have utilised CRM's services (Figure 2). By the end of 2017, there were 1110 new and ongoing ISRs and more than 1900 skilled jobs (versus the 1000 set) created in the clinical research industry before the projected 2020 timeline. These numbers far surpass the KPI set for CRM.[10]

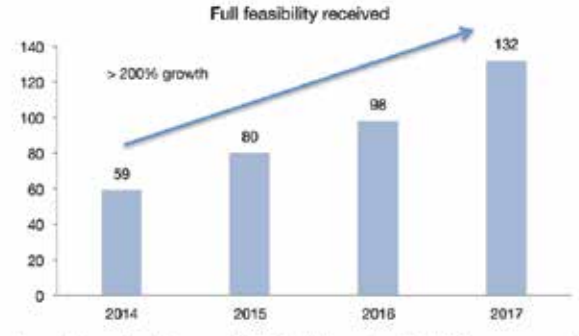

Figure 3: The number of requests for full feasibilities received by CRM from sponsors and CROs from 2014–2017

The reported number of full feasibilities received by CRM from sponsors and CROs showed an increasing trend from 2014 to 2017 with more than a twofold growth (Figure 3). Besides offering this service on a complimentary basis, sponsors and CROs have also recognised CRM's capability and timeliness in reverting a feasibility assessment and have therefore approached CRM in most of their enquiries.

Conclusion

Compared to the current standard working model of ISRs wherein individual sponsors and CROs attempt to conduct clinical trials without a centralised organisation, CRM offers a new paradigm as well as value proposition. The uniqueness of CRM is that it forms an overarching collaborative force between all the different stakeholders involved in the clinical trial ecosystem – sponsors, CROs, government bodies, regulatory agencies, ethics committees, institutional research facilities and private healthcare facilities.

Through its various strategies and activities, the model allows for an integrative approach to transform the ISR industry into a business model with an efficient business management perspective and added dimensions such as marketing and business development, all within a framework that is supported by a country's legal and ethical framework. As the target year 2020 approaches and as CRM continues to expand and gain experience, it offers a working model that may be replicated in other countries within the region that seek to build an efficient and thriving clinical research ecosystem.

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HOSPITAL MIRI

- Miri Hospital is a Secondary Hospital providing services in the north zone of the state of Sarawak.
- The services provided are in terms of patient care to the community.
- Miri Hospital is located about 2.5km from Miri city centre and covers an area of 87.11 acres.
- It began operations on May 6 1995, officially opened by Chief Minister Of Sarawak Tan Sri Pehin Datuk Patinggi (Dr) Haji Abdul Taib Bin Mahmud on 30 August 1996.

OUR FAMILY


HOSPITAL MIRI
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"Melayan Anda ...
Layanan Kekeluargaan"

SPECIALTY

- Accident & emergency
- Anesthesiology
- Dermatology
- Forensic
- Medical
- Nephrology
- Obstetrics & Gynaecology (O&G)
- Ophthalmology
- Oral surgery
- Orthopaedic
- Otorhinolaryngology
- Pathology
- Pediatric
- Psychiatry
- Radiology
- Rehabilitation
- Surgical

CRC Hospital Miri

CRC Office

Officially launched by YB Datuk Lee Kim Shin, Sarawak Assistant Minister of Communication & Sports on 10th February 2012 accompanied by Dr Goh Pik Pin, Director of National CRC, Dr Chin Zin Hing, Deputy Director JKNS & Dr Jack Wong Siew Yu, Director of Hospital Miri.

Located at:
Ground Floor,
Front Porch of Nurses Hostel,
Miri Hospital.

CRC Seminar Room

CRC Seminar Room was officially launched on October 2017 and are allowed to accomodate a maximum number of 30 people. It can be used for the purpose of teleconferences, meetings, courses and webinar sessions.

Installed equipments:
1. Projector
2. 2 speakers with sound system
3. Wi-fi access (UNIFI)
4. Storage access

CRC Laboratory (Procurement from 2013 - 2017)

1. Pharmaceutical refrigerator +2 - +8 degree celsius
2. Pharmaceutical refrigerator -20 degree celsius
3. Pharmaceutical refrigerator -80 degree celsius
4. Pharmaceutical refrigerator -40 degree celcius
5. Refrigerate centrifuge
6. 5 Refrigerator temperature logger
7. PCR Machine
8. CCTV
9. Alarm & communication system for all fridges & freezers
10. Uninterrupted power supply (UPS)

Clinical Examination Room for CRC

Officially launched on December 2017. Located in front of Klinik Pakar 2, Miri Hospital. Installed equipments:
1. Consultation table
2. Examination table
3. Clinical wash-hand basin

ACCOMPLISHMENTS

Year 2013
- Investigator Initiated Research – **6**
- Feasibility – **4**
- Publications – **2**
- Industry Sponsored Research – **1**

Year 2014
- Investigator Initiated Research – **5**
- Feasibility – **7**
- Industry Sponsored Research – **1**

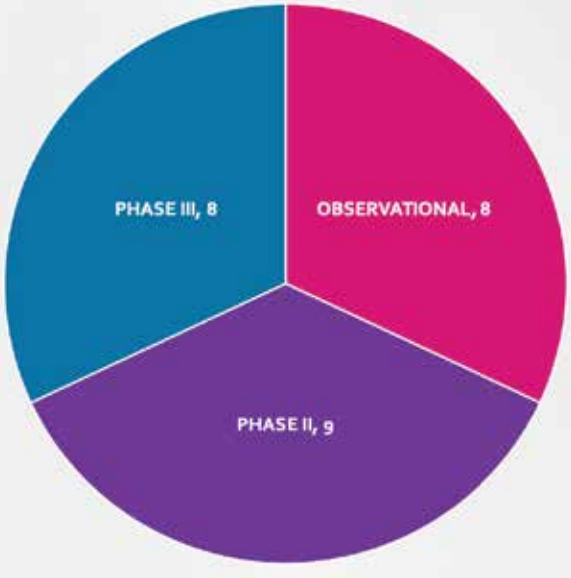
Year 2015
- Investigator Initiated Research – **7**
- Feasibility – **14**
- Publication – **5**
- Industry Sponsored Research – **7**

Year 2016
- Investigator Initiated Research – **6**
- Feasibility – **21**
- Publication – **6**
- Industry Sponsored Research – **5**

Year 2017
- Investigator Initiated Research – **52**
- Feasibility – **21**
- Publication – **18**
- Industry Sponsored Research – **9**

SPONSORED RESEARCH IN HOSPITAL MIRI

Site Overall Involvement in Clinical Trials (All Sponsors)



THERAPEUTIC AREA	2015	2016	2017	2018
CARDIOLOGY	1	0	0	0
ENDOCRINOLOGY	1	0	0	0
PEDIATRIC	0	0	0	2
INFECTIOUS DISEASE	0	2	2	2
RESPIRATORY DISEASE	2	0	0	1
HEMATOLOGY	0	1	0	0
ONCOLOGY	0	0	1	0
NEPHROLOGY	1	0	0	0
O&G	0	0	0	1
OPHTHALMOLOGY	1	0	0	0
EMERGENCY &TRAUMA	1	0	0	0
ORTHOPEDIC	0	0	1	0
PSYCHIATRIC	0	0	0	0
NEUROLOGY	0	0	0	1
ONCOLOGY	0	0	1	0

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PROTOCOL DEVIATION WORKSHOP

The Protocol Deviation (PD) Workshop is for participants who are involved in clinical trial. The workshop is interactive and involves discussion on the current PD trend and the importants of addressing PD among investigators and research team.

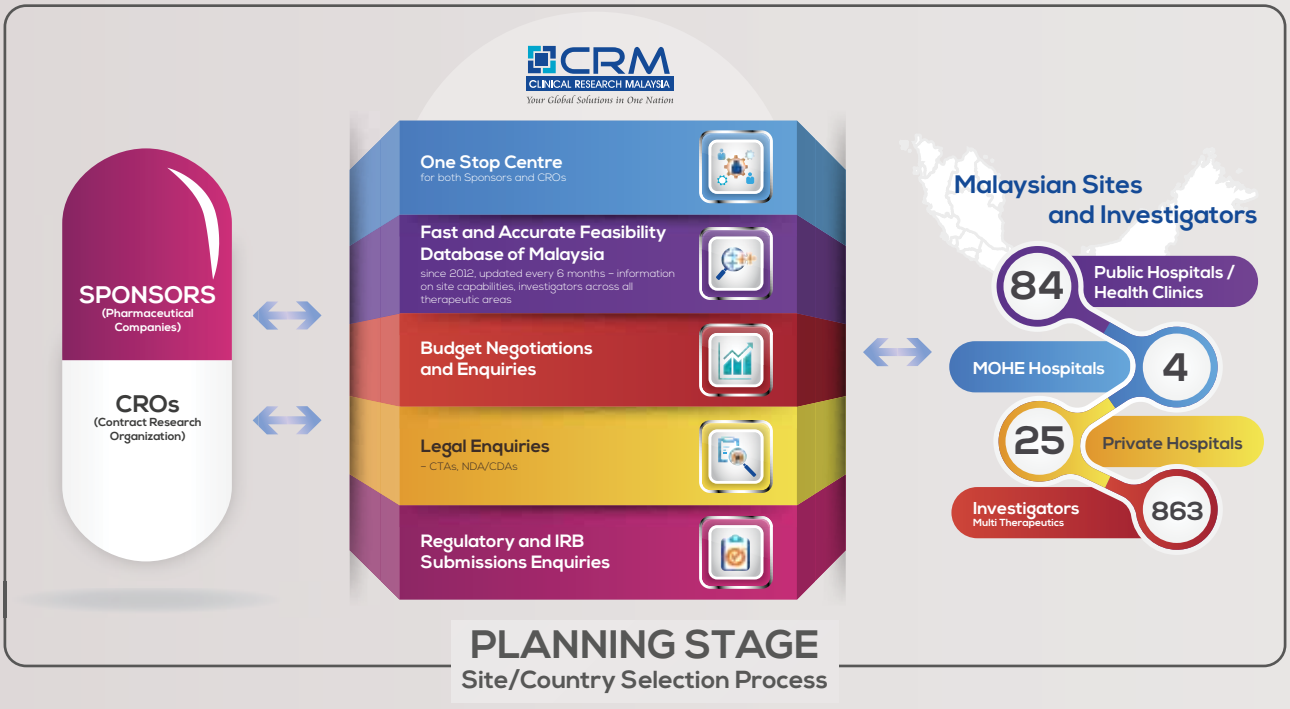
The speakers will share their experience by providing PD examples and tips in handling and preventing PD. Participants who completed the training will be awarded certificates.

Who Should Attend?

- Principal Investigators
- Sub-investigators
- Clinical Study Coordinator
- Research Nurse
- Quality team from investigative site
- Good Clinical Practice certified clinical staff who will be involved in upcoming clinical trial
- Any clinical staff who are currently involving in clinical trial and any interventional studies at investigative site

join now
COMPLIMENTARY REGISTRATION

To find out available workshop, please visit
www.clinicalresearch.my/protocol-deviation-workshop



CRM'S ROLES AND SERVICES IN A NUTSHELL

Recruitment is Everything in a Trial!

By Soon Wen Xian, a medical graduate from Volgograd State Medical University, a Clinical Research Associate at an international pharmaceutical organization based in Singapore.

There are many stages in a clinical trial, for example: feasibility study, start up, active recruitment stage, maintenance stage and study closure. Each stage of a trial is important, but the recruitment process is undeniably the most important part. Because if there is no patient being recruited, there will be no data to analyse and without data, the trial will not meet any objectives. That is why recruitment process plays a very important role in ensuring a successful clinical trial. Recruitment rate is almost always the main issue in a trial. If we can speed up the recruitment rate, not only would we have the results faster, we would also be able to reduce the cost of the trial. In order to make recruitment process a successful one, both site member and sponsor must know their roles well. For this issue, I would like to share how we can make a trial recruitment process easier, faster, and more effective.

What can a sponsor do to speed up the recruitment process?

In my opinion, a CRA (Clinical Research Associate) should discuss recruitment plan with the site not only during the feasibility study but also during submission or SIV (site initiation visit). During feasibility study, a CRA should understand where potential subjects can be located. They may be in the emergency department, found during clinic day or maybe there are some potential subjects that will be taken in by other departments. If the potential subject was taken in by other departments, CRAs can possibly create a brochure or poster to be given to the related department. By having these brochures around, this might remind the department to refer the potential subject to the investigator team. The brochure or poster can be displayed at the department wall or on the doctor's table. If the site approves of the idea, the CRA will have to discuss with the sponsor as the brochure and poster may need to be sent to the ethics committee for approval.

Other than brochures or posters, a CRA could also suggest for a briefing session with the relevant department medical staff. Sometimes, investigators may not be able to spare time for a presentation, but a CRA can proactively get the investigator's approval to approach the related department. In Malaysia, all departments have CME session and CRAs can take about 15 minutes during the meeting to present on the trial and request the department to refer potential subjects to their investigators.

The most effective way to get referral patients from other departments is to get 1 or 2 of the doctors there to be involved as sub-investigators. This will make the doctors feel more involved in the trial and they will be more proactive in looking for potential subjects. This will also create a good environment at the site and encourage more doctors to be interested and involved in clinical research. All this while, clinical research always seem like is a secret mission where – other than study team members – all the other doctors have no chance to get involved. By changing the environment, this will create awareness of clinical research in the hospital.

If an investigator suggests approaching other hospitals for referral, a CRA should always have the referral letter template with him/her. Investigators will only need to fill up the template and print the letter with the site letter head, then it will be ready to send to other hospitals. Most of the time, the letter does not need approval from the ethics committee.

Other than providing support to site on the recruitment process, a CRA should also constantly share the recruitment status of the country and region. The status should be sent to all sites on a monthly basis or fortnightly. When sites received the email, they will know that the CRA is monitoring the recruitment process closely. If there is any site in Malaysia that has recruited a subject, the CRA should share the news to all sites acknowledging the effort. This method helps a lot as it will create awareness among all the sites in Malaysia.

What can site staff do to improve recruitment process?

Recruitment process depends on the protocol design. Sometimes, the protocol design allows site staff to do pre-screening before the trial even started. This is because the potential subject may be having a follow up visit to the site. Site staff should be able to review the medical note to allocate those potential subjects. Once the trial

is ready for screening, site staff can start contacting subjects to arrange for screening visit. This is the fastest and most effective way to screen as the subject is already in the patient bank.

The most challenging part of recruitment process are those protocol designs that will allow only the newly diagnosed patients to be recruited. In this case, sites will have to wait for the potential subject to come on a random day and site staff must catch the subject during the visit. Another challenging way to recruit is for the site staff to review all clinic patients every day so they do not miss any of them. Other than this, investigators should arrange 2 days in a week to meet up with all the doctors in the department to discuss regarding the criteria of the patient for the recruitment. This will make the whole department aware that a trial is actively looking for patient.

During the process, it is recommended that Study Coordinators (SC) document the patients they have seen and state why certain patients are not eligible. This is very important because firstly, this is to document the efforts that site staff had put in. Second, from the list of patients, we can analyse which criteria is the most challenging for the recruitment process and thirdly, some trial will even pay for this effort!

Site should randomize a subject within 3 weeks after site is ready. If site is still facing difficulty to recruit subjects, a meeting should be scheduled between the sponsor and site staff. During the meeting, CRA and site staff should discuss on the list of patients they have pre-screened but are not eligible. Sometimes, site staff may misinterpret causing site to lose potential subjects. Other than reviewing the patient list, CRAs should also share the recruitment status of other sites. It may be that other sites are able to recruit patients and have found a useful method to allocate potential patients. Plus, by sharing other sites' recruitment status, this will encourage the lesser recruiting sites to be more aggressive in their recruitment process.

What other ways can we try in Malaysia to improve recruitment process?

In my opinion, we should try to opt in using social media to share what kind of trials are currently available in Malaysia. As we know, all trials conducted in Malaysia must be registered in the NMRR website and this is a public website. Some of the trial information are freely available to read in the website. If there is an organization that can actively promote in social media on the kind of trials that are currently recruiting in Malaysia, this will really help in boosting the recruitment rate as many of our citizens do not know about clinical research and do not know how to get involved in clinical trials. Clinical research can really benefit patients especially when it comes to cancer patients. Current treatment for cancer disease can be very expensive and may not be effective but patients who are being treated in a clinical trial are treated for free and may be using a more effective treatment than currently available. Moreover, patients will be closely monitored by investigators as this is required by the protocol. Usually the patient will undergo an imaging scan for tumour status every 9 weeks and will have blood test every 3 weeks. For patients that are not participating in clinical trials, they may not be having this kind of structured and routine procedure as these procedures are costly.

Recruitment is everything for a trial and if we can perform well on the recruitment process, more trials will come to Malaysia.

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GCP REFRESHER WORKSHOP

Good Clinical Practice

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View upcoming GCP Refresher Workshops at
www.clinicalresearch.my/gcp-refresher

"The GCP certification itself is challenging for me, but for this refresher course I find it very interesting and I gain more understanding through the training videos. I'll encourage my fellow clinicians to attend this course"

Dr. Rohayah Ismail
FMS, Klinik Kesihatan
Sentul, Kuala Lumpur

"I took my GCP 9 years ago, and I stop doing research for a while. Through this GCP refresher course, I found that it's important to look back at the guidelines and at the same time gain experience from fellow investigators"

Dr. Mohd Fauzi Adbullah
FMS, Klinik Kesihatan
Kuah, Kedah

The GCP Refresher workshop is a customized training provided for anyone who has previously completed the GCP training that is approved by the National Committee for Clinical Research (NCCR) and/or anyone that are GCP certified. This one day programme is dedicated to enhancing the competence of investigators and research team.

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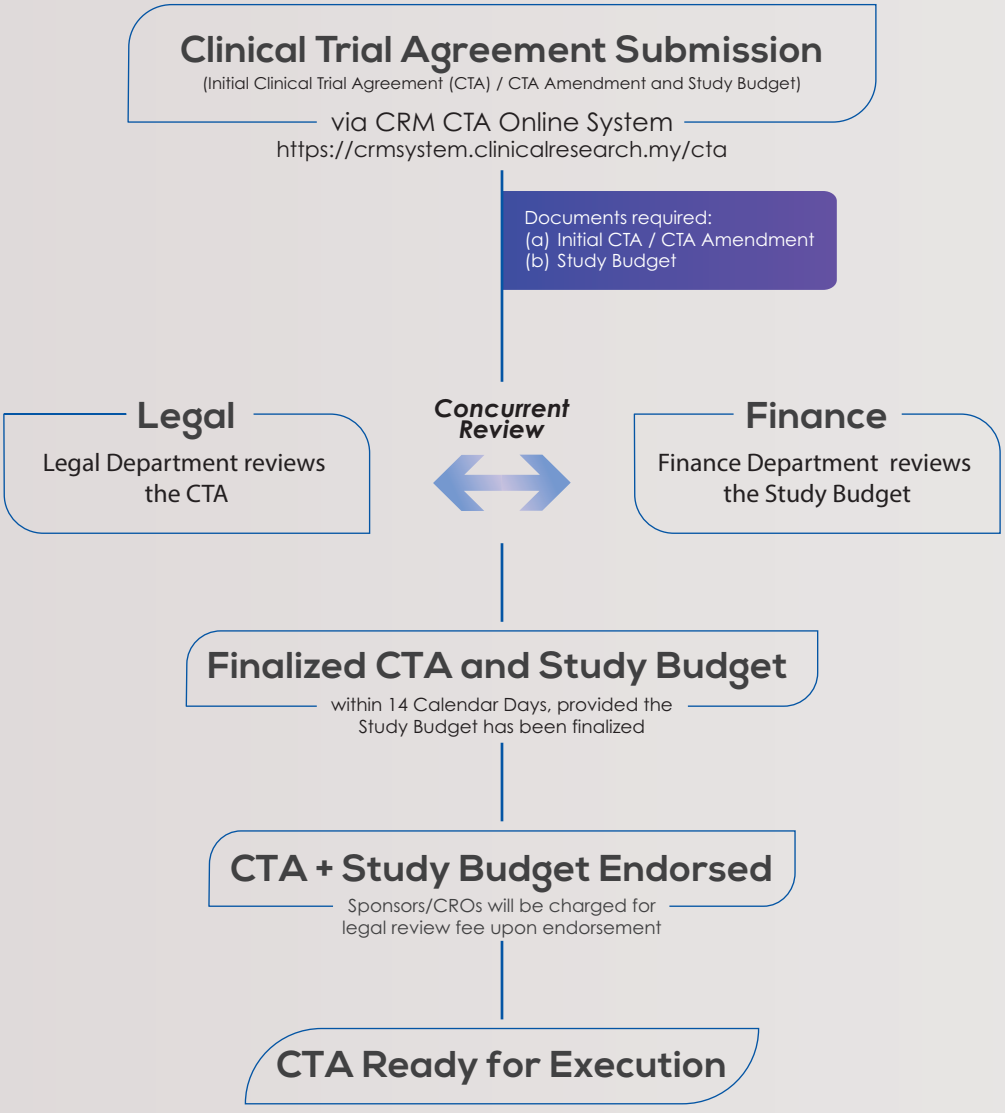
CLINICAL TRIAL AGREEMENT REVIEW PROCESS



REMARKS

Legal Department is responsible to review the CTA and ensure the following are expressly stated in the CTA (below list is not exhaustive):
(i) The applicable law and ICH-GCP regulation are respected;
(ii) Malaysian law as the governing law;
(iii) Settling of dispute by way of Arbitration at AIAC Malaysia or litigation in Malaysian court;
(iv) Indemnification clause;
(v) Confidentiality and privacy.

CRM in Photos

Meeting with AstraZeneca, 14 January

Meeting with Brill Pharma, 28 January

First meeting between local & international Scientific Review Panel (SRP) for Phase 1, 14 February

Visit by St George's University and QuantuMDx, 19 February

Meeting with Clinmark, 19 February

CRM's Office Launch by the Minister of Health, Malaysia, 26 February

Visit to ClinActis, 4 March

4th National Hepatitis Conference 2019, 7 - 8 March

Meeting with AdipoLABs Healthcare Sdn Bhd, 9 March

Meeting with Kuala Lumpur Sports Medicine Centre, 9 March

Healthy Volunteers' Registries talk by Dr. François Bompart, 9 March

Study Coordinators Workshop @ CRM National Conference 2019, 18 January

Meeting with DNDi, 17 January

ISO 9001-2015 Certification by SIRIM QAS International, 19 January

Meeting with Prostacare, 22 January

Meeting with IMU, 30 January

Meeting with Merck Sharp & Dohme (Malaysia), 7 February

Meeting with Orchid Lide Sdn Bhd, 13 February

CRM 1st Board of Directors Meeting 2019, 26 February

MoU between CRM & NUH (Singapore), 26 February

MoU between CytoMed, 26 February

Patient Recruitment Strategy Workshop at Hospital Sultan Ismail, 7 March

Meeting with Singapore's Agency for Science, Technology and Research (A*STAR), 7 March

Meeting with Robert Kuok Foundation, 7 March

1st GCP Symposium Progress in Asian Clinical Trials, 12 March

Meeting with Gilead Sciences, 13 March

Healthcare Meeting by JETRO (Japan External Trade Organization), 13 March

Grant Writing Workshop by Dr. Albiruni Razak, 4 - 5 March

CRM presented Malaysia's value proposition to Japanese Biotech Companies, 12 March

Visit by UK in Malaysia - British High Commission Kuala Lumpur, 1 April

Touch Base with Merck, 5 April

Meeting with iPharm, 10 April

Meeting with Family Health Development Division, Ministry of Health Malaysia, 10 April

I AM AWARE Roadshow Hospital Putrajaya, 11 April

Meeting with Cancer Research Malaysia, 26 April

GCP Refresher Workshop in Hospital Kuala Lumpur, 29 April

Meeting with Tigermed, 14 May

Meeting with Novo Nordisk, 16 May

Meeting with StemLife Berhad, 16 May

Visit to Premier Research, 17 May

Meeting with Pfizer Taiwan & Malaysia, 27 May

Train the Trainer for CRM's Regional Managers, 14 - 15 June

Meeting with Aesculape CRO Sdn Bhd, 17 June

NHAM-CRM Research Track 2019, 13 April

Nurturing New Talent (NNT) in Sponsored Research in Hospital Selayang, 30 April

NERCIM, 17 April

CRM Investigator Dialogue 2019, 24 April

CRM in Photos

CRM Industry Dialogue 2019-1, 24 April

Research Proposal Writing Workshop
by Dr. Masliza Mahmod, 19 - 20 June

Meeting with Astellas Pharma Malaysia, 8 April

Meeting with Pharmaniaga Berhad, 8 April

Meeting with Covance, 18 April

GCP Refresher Workshop in
UiTM Sungai Buloh, 24 April

Visit by H.E. Ibete Fernandez Hernandez
the Cuban Ambassador to Malaysia, 24 April

Meeting with Merck Sharp &
Dohme (MSD), 15 May

Scientific Review Panel (SRP
for First-in-Human studies, 15 May

Parexel Quarterly Alliance Site Update, 16 May

Visit to Health Sciences Authority (HSA)
Singapore, 17 May

Received Provisionally Registered Pharmacist
attachment with CRM from Kotra Pharma, 24 May

Meeting with N2W Corporation Sdn Bhd, 24 May

DIA 2019 Global Annual Meeting
in San Diego, 24 - 26 June

Meeting with Sunway Medical Centre, 19 June

DNDi Hari Raya Open House &
15th Anniversary Celebration, 20 June

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CRC
CLINICAL RESEARCH CENTRE
HOSPITAL KUALA LUMPUR

HOSPITAL KUALA LUMPUR

4th RESEARCH DAY and Clinical Trials Day 2019

29 AUGUST 2019

Auditorium, Hospital Wanita dan Kanak-Kanak Kuala Lumpur

www.clinicalresearch.my/CTD19

#IAMAWARE #CLINICALTRIALSDAY2019 #HKLResearchDay2019