Guide to

BA/BE Centres

in Malaysia

Ver. 1, May 2015

MINISTRY OF HEALTH MALAYSIA

CRM

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Find out how the Government of Malaysia supports the clinical research industry through Clinical Research Malaysia.

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CRM IN BRIEF

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Clinical Research Malaysia (CRM) is a non-profit organization wholly owned by the Ministry of Health Malaysia (MOH). CRM was established in June 2012 to position Malaysia as a preferred global destination for industry sponsored clinical research (ISR), and to provide a range of services as an enabler and facilitator to the industry and medical fraternity.

By working with other stakeholders both domestically and internationally, CRM strives to improve the Malaysian ecosystem to support growth in the number of ISR trials being conducted, facilitate the needs and requirements of industry players, grow the pool of capable investigators and support staff and trial sites, and to improve their capabilities and competencies to conduct high quality ISR trials.

With the MOH's backing and clear knowledge of the local clinical research environment, CRM is able to provide sponsors (primarily from the pharmaceutical, biotech and medical device industries) and contract research organizations (CROs) with an extensive range of services that includes:

- Feasibility Studies
- Investigator Selection
- Review of Clinical Trial Agreements
- Advice on Trial Budgets
- Management of Trial Budgets
- Placement of Trained Study Coordinators
- Updates on Local Laws, Guidelines & Regulations
- Assistance with Problem Resolution

CRM also undertakes marketing and promotional activities to build industry awareness about the opportunities and advantages of conducting ISR trials in Malaysia, and to strengthen public and patient awareness about the benefits of participating in clinical trials.

FOREWORD

Bioavailability/bioequivalence (BA/BE) studies made up one-third of the total number of interventional and observational industry sponsored trials in Malaysia in 2014. In fact, the number of BA/BE studies conducted in Malaysia has increased 21%, from 56 studies in 2013 to 68 studies in 2014. The conduct of these studies are gaining popularity due to the large growth of production and consumption of generic drugs. Generic drugs represent approximately 50% of the total consumption in many European countries and the USA, while in Asia, the generic drug market is growing strongly.

The publishing of this "Guide to BA/BE Centres in Malaysia" marks another milestone in our efforts to boost the numbers of industry sponsored clinical trials conducted in our country. We feel that BA/BE studies can spearhead the conduct of pharmacokinetic and pharmacodynamic investigations, generate knowledge and experience among researchers, and prepare our medical professionals for more complex early phase clinical trials.

With a matured and transparent regulatory framework, strong intellectual property protection, Good Clinical Practice-certified investigators and hospital-based BA/BE units, Malaysia does have what it takes to grow into a preferred destination for BA/BE studies.

I am confident that this guide will achieve the objectives that we have in mind and will help stimulate the conduct of more BA/BE initiatives in the future. The guide was prepared on very short notice and we will continue to further improve upon it.

Finally, I hope you find this "Guide to BA/BE Centres in Malaysia" informative and useful.

DR. AKHMAL YUSOF
Chief Executive Officer
Clinical Research Malaysia (CRM)

CRM bulletin

The CRM Bulletin is published four times a year with a print run of 3000 copies per issue. These are delivered free-of-charge to a local and foreign readership base comprising of: Doctors and investigators (public and private); Hospitals (public and private); Sponsors and CROs; Universities and academics involved in clinical research; Medical research centres; Senior government and MOH officials; Clinical Research Centre (CRC) staff and investigators; Ethics Committees, Patient support groups; and selected medical schools.

The print run is complemented by an online subscriber base of 2000 readers currently, who receive an online copy of the CRM Bulletin.

The bulletin's objectives are to spread awareness about Malaysia's capabilities in industry sponsored clinical research (ISR), inform and attract industry players to Malaysia, motivate and educate potential investigators and support staff, build public awareness about the importance of clinical research, and finally serve as a forum to share news and development relevant to all stakeholders.

Other publications by CRM

NCCR bulletin

Guide for Industry

Patient Brochure

get connected

Opportunities for Bioavailability and Bioequivalence Studies in Malaysia

Many drug patents have recently expired or are scheduled to expire in the near future. As a result, many drug manufacturers have expanded their generic drug portfolio, which requires them to conduct bioavailability/bioequivalence (BA/BE) studies that demonstrate that their generic equivalents perform similarly to the innovator drug product. Bioinequivalence and variations in the bioavailability of generics can result in therapeutic failure and/or toxicity, further stressing the importance of developing standards for bioequivalence and bioavailability testing.

In Malaysia, five local BE centres (total of nine clinical and four bioanalytical sites) are listed in the National Pharmaceutical Control Bureau (NPCB) Compliance Programme for Bioequivalence Centres. Located in the major urban centres of Penang, Selangor/Kuala Lumpur and Kuching, these centres are well placed to recruit sufficient numbers of volunteer participants.

Malaysia is the first country in ASEAN to perform inspection and certification for BE centres locally and abroad. This is to ensure that BE studies being conducted satisfy the stipulated Malaysian regulatory requirements as well as international guidelines. These conditions have to be met before a generic product will be registered in Malaysia.

Malaysia's competitive edge for the conduct of BA/BE studies lies in the strong support from the government, stringent drug regulatory policies, diverse genetic pool of human subjects, hospital-based clinical sites, and bioanalytical sites that comply with the OECD GLP (Organisation for Economic Cooperation and Development Good Laboratory Practice) principles.

In 2014, BA/BE studies contributed almost one third of the total number of Industry Sponsored Research (ISR) clinical trials conducted in Malaysia. (more statistics presented on pages 7 & 8)

This "Guide to BA/BE Centres in Malaysia" showcases the country's capabilities in conducting these studies in well-equipped facilities, supported by experienced investigators and research team, as well as laboratories with state-of-the-art equipment for bioanalysis. These are the very foundation required for the conduct of high quality BA/BE studies.

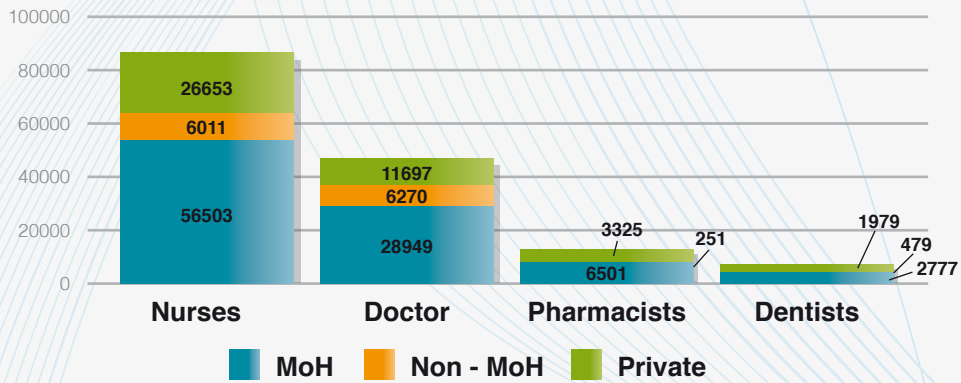
Healthcare Facilities in Malaysia

Healthcare Facilities	Public	Private	Total
Hospitals/Medical Institutions	141	214	385
Dental Clinics	704	1,686	2,390
Health/Medical Clinics	1,039	6,801	7,840

Source: Health Facts, Ministry of Health, 2014

Healthcare in Malaysia is structured into two tiers: a government universal healthcare system covering approximately 60% of Malaysians and a private healthcare system. Private healthcare facilities account for the majority of hospitals, dental and medical clinics in Malaysia

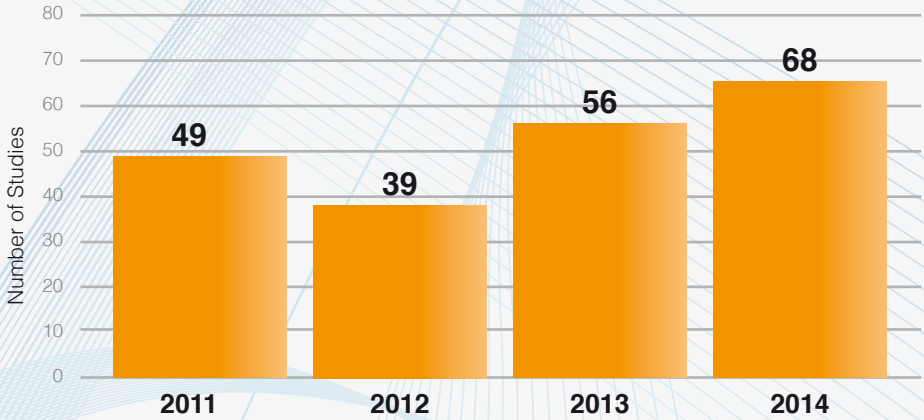
Health Workforce in Malaysia



Source: Health Facts, Ministry of Health, 2014

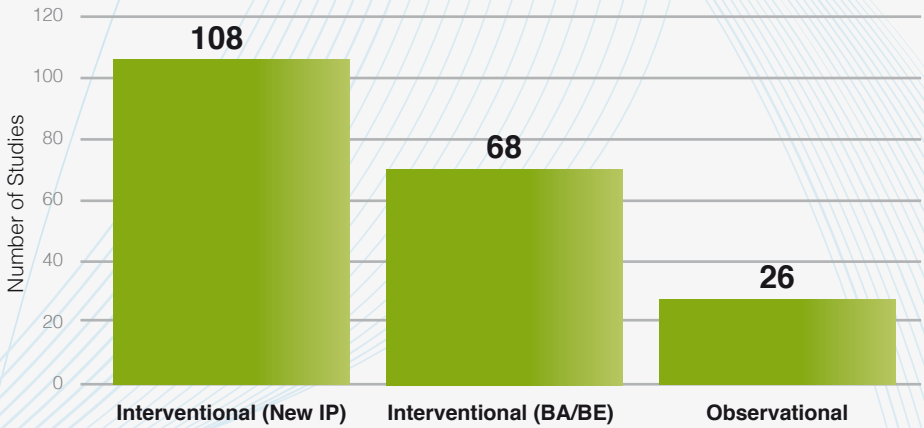
Majority of the healthcare workforce in Malaysia can be found in the government sector. With the overall population of Malaysia hitting 30 million, the doctor-to-population ratio is 1:633 and that of nurses is 1:333.

Approved BA/BE Studies in Malaysia: 2011 to 2014



Between 2011 and 2014, a total of 212 BA/BE studies were conducted in Malaysia.

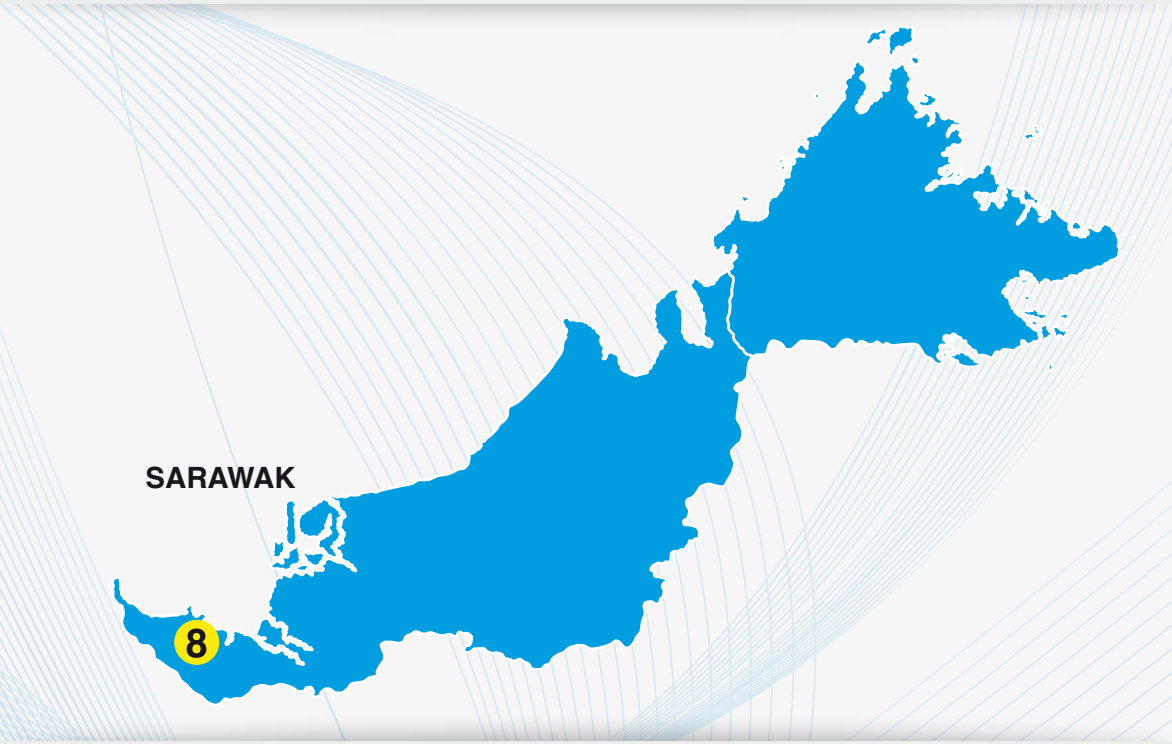
2014 Approved ISR by Classification



108 new interventional trials (including 10 medical device trials) were approved in 2014. This was followed by 68 BA/BE studies and 26 observational studies. About one third of the overall number of industry sponsored trials were BA/BE studies.

BA/BE Clinical & Bioanalytical Sites

1. **Info Kinetics Sdn. Bhd.**
2. **Cardiology Ward, Penang General Hospital**
3. **Clinical Trial Complex (CTC), Advanced Medical & Dental Institute, Universiti Sains Malaysia**
4. **Clinical Research Centre (CRC), Penang General Hospital**



5. **Clinical Trial Unit, Clinical Research Centre, Seberang Jaya Hospital**

6. **Clinical Research Ward, Ampang Hospital**

7. **Bioequivalence Centre, Pharmacy-Hovid Research Sdn. Bhd., School of Pharmaceutical Sciences, Universiti Sains Malaysia**

8. **CRC Research Ward, Sarawak General Hospital Heart Centre**

9. **University of Malaya Bioequivalence and Testing Centre**

10. **Questra Bio-Clinical Research Centre**

Info Kinetics Sdn. Bhd.

Gleneagles Penang & LohGuanLye Specialist Centre, Clinical Research Centre

The clinical sites at both Gleneagles Penang and LohGuanLye Specialist Centre are managed by Info Kinetics Sdn. Bhd., a home grown Contract Research Organization (CRO) which has gained accolades for its international accreditations and worldwide data acceptability. The unique set up of these sites enables the conduct of multiple studies concurrently.

Info Kinetics conducted its first trial in 2001, and over the past three years, it has succesfully conducted 72 bioequivalence (BE) studies and more than 10 Phase I studies at its two clinical sites in Penang. The types of studies conducted here include difficult-to-manufacture generics such as oral inhalation products, modified release products, transdermal delivery systems and sublingual delivery systems. Info Kinetics also has experience and expertise in handling psychotropic and opiates drugs.

Site Support Staff

- 1 Research Physician
- 11 Research Physicians (Part Time)
- 12 Study coordinators
- 14 Research Nurses (Part Time)
- 3 Pharmacists
- 6 Clinical Laboratory Assistants (Part Time)
- 7 Analytical Chemists/Scientists
- 4 QA Personnel

Facilities at Clinical Sites

- A dedicated 40-bedded ward (expandable if required) at Gleneagles Penang and a 24-bedded ward at LohGuanLye Specialist Centre that is well-equipped for clinical trial activities.
- A semi-private meeting room.
- Access controled with internal monitoring cameras, automatic alarm systems and fire & smoke detectors.
- Synchronized digital clocks.
- A temperature-controlled drug storage area with limited access.
- Subject recreation room with sofas, TV and Xbox.
- Two separate consultation suites.

Facilities at Bioanalytical Site

- LCMS/MS, GCMS and HPLC.
- Sample-handling laboratory.
- Refrigerated centrifuge.
- Refrigerators and freezers (–25 °C & –70 °C) for drug and sample storage.

Studies are conducted with the availability of a 24-hour MO & emergency support system in Gleneagles Penang and LohGuanLye Specialist Centre. Blood samples from both sites are analysed in Gleneagles Penang which operates under strict OECD-GLP compliance.

Over 250 BE studies covering most major therapeutic classes have been conducted at these clinical sites since the establishment of Info Kinetics Sdn. Bhd., with the bulk of it being pivotal studies conducted with the intention to gain market authorization in Asia, Europe, Australia, North America and African countries.

Patient recruitment is managed by Info Kinetics, with the availability of a volunteer database of about 1000 potential study participants.





Accreditation & Inspections
Info Kinetics maintains strict ICH-GCP compliance in all its trials at both clinical sites and has been inspected by the French Regulatory Authorities in 2008, Malaysia's National Pharmaceutical Control Bureau since 2006 and the U.S. Food and Drug Administration in 2013.

Info Kinetics' bioanalytical laboratory is ISO/IEC 17025 accredited and OECD-GLP accredited.

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Clinical Site
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Loh Guan Lye Specialist Centre
19 & 21 Logan Road
10400 Penang

Cardiology Ward

Penang General Hospital

The Cardiology Ward located at Penang General Hospital serves as a clinical site for the conduct of Bioavailability/Bioequivalence (BA/BE) studies in the northern region of Peninsular Malaysia. The ward was open in 1998 and conducted its first BA/BE study in 2005. Since its accreditation by the National Pharmaceutical Control Bureau (NPCB), it has conducted more than 20 BA/BE studies ranging from anticoagulants to hypoglycemic agents. The Cardiology Ward earned its reputation as a BA/BE clinical site through the commitment and dedication of its study team and experienced principal investigators, and continues to conduct studies for international sponsors and contract research organizations.

BA/BE studies are mostly carried out during weekends following the admission of subjects on Fridays. The site is able to manage a maximum of 2 studies at one time depending on the study interval. Biological specimens are sent to its bioanalytical site which is located at Pusat Pengajian Sains Farmasi, Universiti Sains Malaysia, Penang.

Facilities at Clinical Site

- 24-bedded ward for BA/BE studies.
- 24-hour medical emergency support by the hospital's A&E team.
- Qualified and capable principal investigators and sub investigators.
- Experienced and competent staff nurses and sisters who are certified in Good Clinical Practice (GCP).
- Support from the hospital's pathology laboratory where biological specimens are stored before being analyzed:
  - Refrigerators and freezers (2–8 °C, –20 °C and –80 °C)
  - Refrigerated centrifuge

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Clinical Trial Complex (CTC), Advanced Medical & Dental Institute
Universiti Sains Malaysia

The Advanced Medical & Dental Institute (Institut Perubatan dan Pergigian Termaju (IPPT)) was established to serve as a platform for advancement in research and education in the medical and dental fields. In line with this main objective, its Clinical Trial Unit (CTU) in collaboration with the School of Pharmacy, Universiti Sains Malaysia (USM), initiated the first bioequivalence (BE) study in December 2012. On 19th August 2013, the Clinical Trial Complex of IPPT was certified by the National Pharmaceutical Control Bureau as a clinical site for the conduct of BE studies.

Since then, the CTU has been actively intensifying its clinical facility and has successfully conducted numerous BE studies. Between 2012 and May 2015, it has conducted a total of 8 BA/BE studies and several industry-sponsored clinical trials with internationally renowned pharmaceutical organizations.

The team members of IPPT CTU consist of GCP-certified personnel who are committed and dedicated in providing state-of-the-art clinical services for researchers, contract research organizations and pharmaceutical industries involved in BE studies. This clinical site comes under the management of the Clinical Services Division where a Day Care Ward of the CTC is used for the conduct of BE studies.

Facilities at Clinical Site

- 18-bedded ward (fully furnished with wardrobes and drawers).
- Fully air-conditioned Day Care Facility.
- 4 toilets with shower facilities .
- Additional 9 convertible chair-bed.
- 2 nursing counters.
- A room for staff nurses.
- A dedicated counselling and prayer room.
- A fully equipped procedure room.
- A treatment room.
- Pantry.
- 4 sets of computer with individual printer facility.
- 4 units of telephone.
- LCD television for subject's viewing pleasure.
- Vital equipment to support clinical trials/research activities/emergency responses:
  - Resuscitation trolley
  - Vital signs monitor
  - Sterile consumables
  - Vein viewer
  - Stretcher
  - Wheelchair
  - Regular Predictive and Preventive Maintenance (PPM)
  - Basic emergency tools (e.g. fire distinguishers, fire alarms, emergency exit signage, etc.)
- Intensive care facilities.
- A 24-hour internal emergency response team to handle emergency cases.

Site Support Staff

- 2 medical officers (GCP-certified).
- 5 nurses (GCP-certified).
- On-call support team that includes laboratory personnel, medical officers, radiographers, head nurses, security personnel and engineering team (for after-hours unexpected glitches).

Advanced Diagnostic Laboratory (ADL)

ADL is one of the services under the Clinical Services Division located in the Clinical Trial Complex (CTC). ADL provides laboratory services in the fields of Haematology, Chemical Pathology, Genetics, Histopathology and Cytology, Microbiology and Transfusion Medicine. Its patrons are from IPPT outpatient clinics, government hospitals, private hospitals and private laboratories. ADL has been actively involved in the activities of MS ISO 15189:2007 since 2008 and 5S activities since 2012 and has been accredited for both quality management awards.

Imaging Unit

The Imaging unit of this centre is equipped with a CT (computed tomography) scan, MRI (magnetic resonance imaging), ultrasound, as well as minimally invasive, image-guided interventional procedures. Many imaging protocols and procedures performed in this unit are rarely done in other institutions. All imaging examinations are protocoled, performed, and interpreted by radiologists.






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Clinical Research Centre (CRC)

Penang General Hospital

The Clinical Research Centre (CRC) at Penang General Hospital was established in 2001 and has been operational since 2003. The centre received accreditation as a Bioequivalence (BE) clinical site in January 2015. The first BE study was lead by Prof Dr. Peh Kok Khiang (Principal Investigator) and Dato' Dr. Ong Loke Meng (Site-Principal Investigator).

This clinical site is ready to receive more studies over the next few months, with the next BE study expected to be conducted in August 2015. The studies are conducted during weekends by experienced and competent Principal Investigators, Sub-Investigators and senior staff nurses who are certified in Good Clinical Practice (GCP). Biological specimens are sent to its bioanalytical site which is located at Pusat Pengajian Sains Farmasi, Universiti Sains Malaysia, Penang.

Facilities at Clinical Site

- A well-equipped 24-bedded clinical trial ward.
- 24-hour medical emergency support.
- Ultralow biochemical freezers and pharmaceutical refrigerator (2–8 °C).
- Synchronized digital clocks.
- A dedicated vaccine refrigerator.
- Refrigerated centrifuges (2000–4000 rpm and 4500–18000 rpm).
- Controlled access to the clinical trial ward.

Clinical Research Centre (CRC), Penang General Hospital

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Clinical Trial Unit, Clinical Research Centre

Seberang Jaya Hospital

The Clinical Trial Unit (CTU) of Seberang Jaya Hospital was established in 2012, and saw its first bioequivalence study completed by March 2013. To date, the CTU has undertaken 11 bioequivalence studies successfully, and is poised to become a major player in the northern region.

Facilities at Clinical Site

- 24-bedded ward (36 beds upon completion of the new ward extension).
- A refrigerated and standard centrifuge.
- Pharmaceutical refrigerator and freezers (–40 °C and –80 °C) for storage of plasma samples and investigational medicinal products.
- Temperature monitoring system (in the laboratory as well as in each equipment).
- Controlled-access.
- 24-hour closed circuit television monitoring system.

The CTU receives strong support from other hospital departments, particularly the A&E Department (Emergency Medical Technicians, EMTs, on standby) during the conduct of bioequivalence studies and is situated in close proximity with the Hospital's Intensive Care Unit. Biological samples are sent for analysis at the Bioanalytical site located at Kompleks Eureka, Universiti Sains Malaya, Penang, headed by Prof Dr. Yuen Kah Hay.

Dr. Azlina Muhamad Radzi who is the Sebarang Jaya Hospital Director, has been very supportive of the unit as well as in its conduct of BA/BE studies. She has stationed four medical doctors permanently in the unit, who work together with two pharmacists, three nurses, and four research officers. Most medical staff are certified in Good Clinical Practice (GCP) and Basic Life Support. The clinical site also enjoys the luxury of the service of a qualified Project Manager who has accreditation in PRINCE2 (Projects IN Controlled Environments).

The CTU research culture centers around the theme of "Today's Research is Tomorrow's Treatment". They aspire to become the centre of excellence in the northern region, and with unsurpassed commitment they will reach this goal.

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Clinical Research Ward

Ampang Hospital

The Clinical Research Ward (CRW) at Hospital Ampang is the first Phase I clinical facility established by the Ministry of Health to conduct various types of early phase clinical studies including first-in-man trials and bioavailability/bioequivalence (BA/BE) studies. The CRW began its operation in April 2011 and is currently managed by the hospital's Clinical Research Centre (CRC). The facility's main objective is to conduct phase I clinical trial in compliance with international standards and guidelines, as well as to develop and expand early phase clinical trials in the country.

This facility has 46 beds and is located at level 7 of the hospital's main building. Equipped with state-of-the-art medical facilities for phase I clinical research, the in-hospital location guarantees that every trial conducted is supported by 24/7 access to emergency response teams. Its operation is managed by a team of well-trained professionals including technical advisor, head of unit, project manager, pharmacists, study coordinators, clinical manager and clinical research nurses.

Facilities at Clinical Site

- 46-bedded inpatient ward.
- Screening clinic.
- Sample processing room equipped with centrifuges, a laminar flow cabinet and freezers (-86°C, -80°C and -40°C).
- Clinical examination room.
- Pharmacy room equipped with a pharmaceutical fridge (2-8°C).
- Fireproof documentation cabinets.
- GPS-synchronized clocks in every room.
- Recreational room (for trial participants).
- Prayer hall.
- Internet access for patients.
- Access control unit.
- CCTV.

Clinical Research Ward, Ampang Hospital

Clinical studies at CRW are closely controlled and monitored to the highest standard and with maximum safety measures to ensure adherence to international and local Good Clinical Research Practice standards.

The CRW is one out of 10 BA/BE sites (with an external bioanalytical site) which has been accredited by NPCB as being a BA/BE compliance site. Among the services provided by this facility include protocol development, ethics and regulatory submission, import license application, patient recruitment, clinical conduct and site project management.

CONTACTS

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Dr. Damenthi Nair

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Bioequivalence Centre, Pharmacy-Hovid Research Sdn. Bhd., School of Pharmaceutical Sciences
Universiti Sains Malaysia

The Bioequivalence Centre at the School of Pharmaceutical Sciences, Universiti Sains Malaysia (USM) was established in 1990 to conduct bioavailability and/or bioequivalence studies. It is the first centre to conduct such studies in Malaysia. The Centre was initially set up to cater to the needs of the Malaysian regulatory authority to test pharmaceutical products (arising from product complaints) as well as to support the local pharmaceutical industry.

Since then, the Bioequivalence Centre has expanded into a well-established regional facility to conduct bioequivalence and bioavailability studies needed to support registration of pharmaceutical products in many countries including Malaysia, Singapore, Australia, Philippines, Cambodia, Hong Kong and some of the African countries (eg. Ethiopia).

The Bioequivalence Centre is headed by Professor Dr Yuen Kah Hay who has over 30 years of R&D experience in pharmaceutics & biopharmaceutics as well as clinical research. The Bioequivalence Centre is listed in the National Pharmaceutical Control Bureau, Ministry of Health Malaysia's Compliance Programme for Bioequivalence Centre.

Set Up & Infrastructure
The Bioequivalence Centre consists of three sections, namely the clinical site, the bioanalytical site and the pharmacokinetic and statistical site.

Clinical Site
The clinical phase of studies are conducted in collaboration with two Clinical Research Centres in Malaysia located at Hospital Seberang Jaya in Penang and Hospital Ampang in Selangor. Both clinical centres are GCP compliant and operated by highly trained and experienced clinical investigators. All trials are conducted in accordance to the Good Clinical Practice Guidelines and Declaration of Helsinki and all staff members are GCP-certified.

Bioanalytical Site
The bioanalytical facility is a collaborative effort between the School of Pharmaceutical Sciences, USM and Hovid Research Sdn. Bhd. It is located within the USM campus in Penang and is a full-fledged facility equipped with state-of-the-art triple quadrupole LCMSMS and other HPLC systems with UV and fluorescence detection. The laboratory has expertise in developing sensitive methods using LCMSMS as well as methods for quantifying parent drugs and metabolites.

The laboratory is certified according to the International Organization for Standardization (ISO) standard (MS ISO/IEC 17025). It is staffed by experienced and well-qualified staff to develop and validate bioanalytical methods and analyse biological samples obtained from bioequivalence and other clinical trials. To date, more than 50 validated bioanalytical methods have been developed and the list is growing.

Pharmacokinetic and Statistical Unit
Pharmacokinetic and statistical analysis together with the data management unit is responsible for protocol development and CRF design to ensure compliance of the trial with regulatory requirements. Pharmacokinetics and statistical analysis are conducted using validated software available commercially.

Human Resources
The Bioequivalence Centre is headed by Prof Dr. Yuen Kah Hay who has with him over 30 years of R&D experience including the conduct of Clinical Research. Moreover, the staff members are experienced and well-qualified to conduct clinical trials and are GCP-certified. The team has established expertise in all aspects of clinical trials including protocol development, ethics committee submission and approvals, subject recruitment, randomization schedules, clinical trial management, statistical analysis, data management, interim and final report preparation as well as medical reporting. They are able to handle the planning, management, execution and analysis of various types of clinical trials, ranging from small studies to complex, multi-centre projects.

Services

- Conduct of bioequivalence and bioavailability studies.
- Protocol development.
- Development of Patient Information sheet and Informed Consent Forms.
- Development of Case Record Forms.
- Application to Institutional Review Board and Ethics Approval.
- Clinical Trial Import License application.
- Clinical Trial Exemption application.
- Subject Recruitment.
- Subject Randomization.
- Reporting of adverse events.
- Handling of trial drugs.
- Bioanalytical method development and validation.
- Analysis of drug concentration.
- Data and statistical analysis.
- Report writing.

Audits & Submission

- Recognised by Malaysia's National Pharmaceutical Control Bureau to conduct bioequivalence studies.
- BE reports have been submitted to ASEAN and African countries for successful registration of pharmaceutical products.
- Analytical unit is MS ISO/IEC 17025 accredited and OECD GLP compliant.

List of Bioanalytical Validated Methods

More than 50 bioanalytical validated methods.

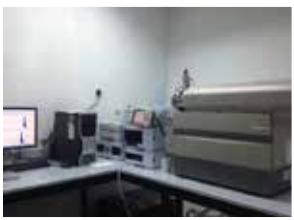
Ethics Committees

The Bioequivalence Centre has access to two independent ethics committees which function according to GCP guidelines and are recognised by the national regulatory authority. These are the Ministry of Health's Medical Research and Ethics Committee (MREC) and USM-Lam Wah Ee Ethics Committee.

Volunteer Database

The database consists of healthy volunteers aged between 18 to 55 years old of diverse ethnicity including Malay, Chinese, Indian as well as from Indonesia including Javanese, Batak, Minangkabau etc.



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CRC Research Ward
Sarawak General Hospital Heart Centre

The bioequivalence (BE) programme of CRC Sarawak General Hospital (SGH) is conducted in Sarawak General Hospital Heart Centre (SGHHC), which itself is situated about 15km away from the main hospital. The BE studies take place in the CRC Research Ward, a fully equipped clinical research ward located at Level 6 of the hospital. The clinical site is recognized by the Ministry of Health (MOH) Malaysia and was listed in the National Pharmaceutical Control Bureau Compliance Programme for Bioequivalence Centres in September 2013.

CRC SGH has developed a partnership with a Sarawak-based Contract Research Organization (CRO), Borneo Kinetics Sdn. Bhd., to complement the study activities. Between September 2013 and May 2015, the Centre has conducted 15 BE studies covering a broad spectrum of pharmaceutical products, from hypertensive to antibiotics. The CRC Research Ward is also tailored to conduct selected Phase I clinical studies.

Site Support Staff

- 6 Medical Officers
- 19 Research Staff Nurse
- 6 Research Pharmacists

Facilities at Clinical Site

- Ward:
  - 24-bedded air conditioned ward (expendable to 36 beds if required), equipped with TV and toilet in each room.
  - 4-bedded room with full monitoring and resuscitation facilities.
- Controlled-access to ward, investigational drug storage room, biosample handling laboratory and archive room.
- On-site biosample handling laboratory:
  - Freezers and fridge equipped with Thermoguard system (–80 °C, –20 °C, 4 °C) and –80 °C portable freezer.
  - Refrigerated centrifuge.
- Investigational drug storage room with humidity and temperature control and a close-circuit television.
- Synchronized digital clocks placed at critical areas.
- Archive room.
- Wifi access.
- Dedicated recreational area with sofas, flat screen TV, DVD player, android media player and games.

Its **bio-analytical** site is at:

Info Kinetics Sdn. Bhd.
5th Floor, Gleneagles Penang,
No. 1, Jalan Pangkor,
10050 Pulau Pinang.

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Clinical Research Centre
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Jalan Hospital,
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University of Malaya Bioequivalence and Testing Centre (UBAT)

The University of Malaya Bioequivalence and Testing Centre (UBAT) started out as part of a research project in the late 1990s when the then Deputy Director of University Hospital, Professor CT Chua, realized that generics were generally sub-standard, that the number of Bioequivalence (BE) studies were steadily increasing and noted the surge in request for BE studies from 2006 onwards. In 2008, UBAT was established. Both its clinical and bioanalytical sites are located at University Malaya Medical Centre (UMMC) and the Department of Pharmacology, University of Malaya, respectively.

Facilities at Clinical Site

- 2 well-equipped clinical/examination ward (each ward with 30 beds).
- ECG machine, blood pressure monitor and the necessary equipment for pharmacokinetic sampling.
- Breath analyzer.
- Urine drug scan kit.
- Drug storage/archive facility.
- CCTV monitoring.
- Temperature-controlled storage area.

Facilities at Analytical Site

- LCMS/MS.
- HPLC.
- Freezers (–80 °C, –40 °C, –20 °C) and refrigerators equipped with a back-up generator system.
- Microbalance.

To date, the centre has conducted over 35 BE studies ranging from studies on various antibiotics to antihypertensives, and has collaboration with numerous local pharmaceutical manufacturers. Its clinical site is able to conduct two BE studies simultaneously with the availability of two separate 30-bedded Examination Wards. The wards are located within UMMC and near to the A&E facilities, with 24-hours access to doctors and the presence of a physician throughout a BE study.

Trained/Experienced Staff

- Principal Investigators
- 4 Clinical Doctors at study site
- 2 Study Coordinators
- 1 Pharmacokinetic Analyst
- 2 Medical Lab Technologists
- 1 Custodian
- 4 Study Nurses

Accreditation

The centre received the BioNexus status in 2009 and continues to enjoy the privileges that comes with the award right up until today. It was also awarded the Skim Akreditasi Makmal Malaysia (SAMM) ISO 17025 on March 2012 and certified as a BE centre by the National Pharmaceutical Control Bureau in December 2012.

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Tel: +603-7967 6621

Clinical Site
Clinical Examination Ward 2
University of Malaya Medical Centre,
50603 Kuala Lumpur

Bioanalytical Site
University of Malaya Bioequivalence and Testing Centre (UBAT)
Department of Pharmacology,
Faculty of Medicine,
University of Malaya,
50603 Kuala Lumpur.

Tel: +603-7967 6620
Fax: +603-7967 4791

Questra Bio-Clinical Research Centre

Questra Clinical Research Sdn. Bhd., established in August 2011, is an energetic and promising contract research organization (CRO) that aligns its growth strategy with the huge opportunities for clinical research in the Asia Pacific region. It focuses on CRO clinical research services and project management as well as bioavailability/bioequivalence (BA/BE) studies.

Questra Clinical Research is the first CRO to establish the first stand-alone research facility to conduct clinical trials and BA/BE studies in Malaysia. Its facility operates under the Private Healthcare Facilities and Services Act 1998 and occupies an area of 6,300 sq. ft. It houses a fully equipped bioanalytical laboratory, clinical wards, screening clinic, document storage area and training room.

Site Support Staff

- Medical doctors
- Nurses
- Project management team
- Clinical research team

Facilities at Clinical Research Unit

- Clinic:
  - Equipped with C-MagSys Clinic System.
  - Volunteer waiting lounge.
  - Registration area.
  - Height and weight measurement area.
  - Procedure room (blood collection and ECG).
  - Consultation room (physical examination & inform consent taking area).
- Ward:
  - 30-bedded ward (expandable if required).
  - Acute monitoring bed for emergency cases.
  - 24-hours CCTV monitoring.
  - Patient monitor.
  - Emergency trolley.
  - Oxygen cylinder.
  - Defibrillator.
  - Evacuation chair.
  - Suction apparatus.
  - Recreation area with TV and wi-fi.
  - Synchronized digital clocks.
- Pharmacy
  - Drug storage facilities are temperature-controlled with limited access.

Facilities at Bioanalytical Research Unit
The Bioanalytical Laboratory serves as a sample processing area and is able to perform analysis for BA/BE studies. The laboratory is equipped with:

- LCMS/MS
- Nitrogen evaporator
- HPLC
- Fume hood
- Deep freezer (–40 °C)
- Micropipettes
- Laboratory refrigerator
- pH meter
- Refrigerated centrifuge
- Vortex mixer
- Semi-microbalance
- Sonicator
- Analytical balance

Quality Assurance Unit
The quality assurance team ensures SOP compliance in line with the current regulatory requirements and has a dedicated team for auditing of clinical and bioanalytical phases of the study.

Questra Clinical Research is currently applying for inspection from the National Pharmaceutical Control Bureau (NPCB), to be listed in the NPCB Bioequivalence Compliance Programme.

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