Contents

The Clinical Research Centre MOH

- Who are we?
- What do we do? And what are our accomplishments?
- Where do we go from here?
Conceived in the 1990s as the clinical research arm of the MOH; first centre opened in HKL in 2000.

It is one of 6 research institutes under the National Institutes of Health of the MOH

By 2010, the Network of CRCs comprises 17 centres in MOH hospitals. Also getting Private hospitals’ and Universities’ CRCs to affiliate with the Network

Key tasks are to develop
- the capacities to enable high quality clinical research
- Network of sites to provide ready access to a large pool of investigators & patients for research purpose
CRC’s vision & dual missions

For the people’s health & wealth

CRC’s vision is to be leading clinical research organisation in Asia

CRC is both a MOH and Govt organisation

1. As part of the MOH, we share MOH’s broad public health mission: “To Improve patients’ health outcomes through ethical and quality clinical research”

Public health research mission for people’s health

2. As a Government Research institute, we also share responsibility for Malaysia’s critical national mission……. Specifically, to contribute to the development of Malaysia as a favourite site for the clinical research outsourcing industry”

Contract research mission for the people’s wealth
CRC’s 12 objectives

<table>
<thead>
<tr>
<th><strong>Public Health Research Mission</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Promote, initiate and conduct clinical research in Malaysia</td>
</tr>
<tr>
<td>2. Increase funding for clinical research</td>
</tr>
<tr>
<td>3. Strengthen research governance &amp; ethical oversight</td>
</tr>
<tr>
<td>4. Expand the number of Investigator &amp; other research personnel</td>
</tr>
<tr>
<td>5. Strengthen clinical research skills &amp; best practices</td>
</tr>
<tr>
<td>6. Develop research infrastructure</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Contract Research Mission</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>7. Market Malaysia to industry as the preferred trial location</td>
</tr>
<tr>
<td>8. Develop the human capital for the industry</td>
</tr>
<tr>
<td>9. Facilitate access by industry to investigators and patients</td>
</tr>
<tr>
<td>10. Strengthen collaboration and partnering to develop the industry</td>
</tr>
<tr>
<td>11. Develop sound legal framework to govern contract research</td>
</tr>
<tr>
<td>12. Actively manage investigative sites conducting contract research</td>
</tr>
</tbody>
</table>
THE CRC NETWORK
Committed Government Support and Network of excellent health care facilities

As a nation, with our network of public hospitals and primary care clinics, Malaysia has achieved remarkable improvements in health outcomes. Modern private hospitals boast world class facilities. We have also invested in the necessary infrastructure and prepared the legal framework to ensure that Malaysia is the research destination of choice in various clinical therapeutic fields.

Datuk Seri Najib Razak
Prime Minister of Malaysia

CRC Network: 17 Ministry Of Health tertiary hospitals + Major private hospitals + 3 affiliated University Hospital PLUS access to 120 other MOH hospitals

Provide Access to a large pool of investigators & patients for clinical research in Malaysia
Network of CRCs in MOH Hospitals

Providing access to 550 clinical investigators and 17 million patients from diverse therapeutic areas in the public healthcare system in Malaysia
Location of CRCs in Malaysia
ACCESSIBLE SITES

1 STOP CENTRE AS A SINGLE POINT OF CONTACT

1. CRC Perlis
2. CRC Kedah
3. CRC Pulau Pinang
4. CRC Perak
5. CRC Selayang, Selangor
6. CRC Kuala Lumpur

7. CRC Ampang, Selangor
8. CRC Serdang, Selangor
9. CRC Klang, Selangor
10. CRC Negeri Sembilan
11. CRC Melaka
12. CRC Johor Bahru

13. CRC Pahang
14. CRC Terengganu
15. CRC Kelantan
16. CRC Sarawak
17. CRC Queen Elizabeth

INTEGRATING A NETWORK OF CRCs WITHIN AN EXISTING NETWORK OF PUBLIC HEALTHCARE SYSTEM

NATIONWIDE PRESENCE WITHIN HOSPITAL SETTINGS ENABLES EFFICIENT INVESTIGATOR AND PATIENT RECRUITMENTS
CRC Network as central point of contact

A One-stop centre to meet all your needs

- Recruitment of Potential Sites for Clinical Trials
- Facilitate feasibility
- Site Management
- Standard Contract
- Uniform and transparent pricing
- Centre of Information
- Marketing & Promotional Activities
- To Collaborate with Other Stakeholders of Research
Services

- Identify suitable investigators for clinical trials
- Establish & update investigator database accessible online to PHARMA / CRO for information on available investigators by therapeutic area
- Provide resources for site undertaking clinical trial to ensure adequate purpose
- Undertake submission on behalf of PHARMA/CRO
WHAT WE DO
So what does the CRC do?

Four inter-related tasks

1. Develop **Research capacity**
2. Develop **Data Resources**
3. Promote & manage **Contract Research**
4. Support **Investigator Initiated Research**
## 1. Develop Research Capacity

<table>
<thead>
<tr>
<th>#</th>
<th>Research capacity</th>
<th>Status</th>
</tr>
</thead>
</table>
| 1  | **Research Governance & Ethics**  
   *Esp. human subject protection & data confidentiality*                          | Ongoing efforts developing governance framework, structure & culture.                         |
| 2  | Domain expertise                                                                   | MOH investigators                                                                          |
| 3  | Methods & protocol                                                                 | Core competency                                                                             |
| 4  | Project mgt & Research QA                                                         | Core competency                                                                             |
| 5  | **Information Tech.**  
   *key enabling tool for Clinical Res., like Lab for Biomedical research*       | •Document Mgt System  
   •Res. & Publication Repository  
   •Part 11 Clinical Trial systems  
   •IVRS Central Randomization  
   •Information security tech.                                                |
| 6  | Data management                                                                    | In-house/ Outsourced                                                                        |
| 7  | Biostatistics                                                                     | In-house/ Outsourced                                                                        |
| 8  | Medical writing & Publishing                                                       | In-house/ Outsourced                                                                        |
| 9  | **Specialized functions:**  
   Clinical Lab, Safety, Logistics, etc                                              | Outsourced                                                                                  |
The design and conduct of modern clinical research is a complex undertaking. It requires many professionals from diverse disciplines to perform the variety of work processes involved.
# Human resource & Best practices

<table>
<thead>
<tr>
<th>Human resource</th>
<th>Training</th>
<th>Best practice std</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinician scientist</td>
<td>MD. PhD. GRP</td>
<td>Scientific stds. GRP</td>
</tr>
<tr>
<td>Investigators</td>
<td>MD. GCP, GRP</td>
<td>GCP, Helsinki</td>
</tr>
<tr>
<td>Bioethicist/ IRB pro.</td>
<td>Bioethics, IRB admin</td>
<td>Helsinki, GCP, GRP, CIOMS</td>
</tr>
<tr>
<td>Clinical Epi.</td>
<td>MDs and PhDs</td>
<td>Scientific stds, GEP</td>
</tr>
<tr>
<td>Clinical Trialist</td>
<td>MDs and PhDs</td>
<td>Scientific stds, ICH E series</td>
</tr>
<tr>
<td>CRM/ CRA</td>
<td>CCRA</td>
<td>GCP</td>
</tr>
<tr>
<td>Study Coordinator</td>
<td>SRN, CCRC</td>
<td>GCP</td>
</tr>
<tr>
<td>Safety surveillance</td>
<td>Pharmacy</td>
<td>E2, MedDRA</td>
</tr>
<tr>
<td>Trial Supplies</td>
<td>Pharmacy</td>
<td>GMP (Annex 13)</td>
</tr>
<tr>
<td>Info Tech (IT)</td>
<td>Industry cert.</td>
<td>Part 11, ISPE, ISO2700</td>
</tr>
<tr>
<td>Data mgt</td>
<td>CCDM</td>
<td>E6, E9, GDMP</td>
</tr>
<tr>
<td>Lab</td>
<td>MD Path, MLT</td>
<td>GCLP (BARQA)</td>
</tr>
<tr>
<td>Biostatistics</td>
<td>PhDs</td>
<td>ICH E9 and PSI, GSP</td>
</tr>
<tr>
<td>Economics</td>
<td>PhDs</td>
<td>Scientific stds</td>
</tr>
<tr>
<td>Medical writer</td>
<td>MDs and PhDs</td>
<td>ICH E3, ICMJE</td>
</tr>
</tbody>
</table>
Develop Human capital for Clinical Research

1. **Methodological**: Research methods, Biostatistics, Health Economics, etc
2. **Ethics** of Clinical Research for IRB members & Investigators
3. Good Clinical Practice (GCP) certification course
4. ACRP certification program for CRAs & Nurses
5. Biotech Corp’s Internship program
Clinical Research Conference

NIH-NCCR 2010
NIH Scientific Meeting and National Conference for Clinical Research 2010

Advancing Medical Research in Malaysia: the next stage

Date: 2 - 3 June 2010
Venue: The Royale Chulan Kuala Lumpur

Key topics & symposia:
- Research Governance & Ethics
- Regulation of Clinical Research in Malaysia: Update
- Early Clinical Development/ Phase 1 studies in Malaysia
- Biobanking & clinical research
- Stem Cell Research & Therapy
- Healthcare reform
- Healthcare Quality
- Clinical Performance monitoring
- Patient safety
- Patient registries in Malaysia
- Malaysian Healthcare statistics
- Science to Business /Bio-entrepreneurship
- Contract Research Outsourcing (CRO) industry in Malaysia: Update
- Globalization of clinical research & Asia
- Asian Clinical Trial Network (Hong Kong, Thailand, Korea, Japan)
- Therapeutic product evaluation (Device, TCM, Post-marketing surveillance)

Many workshops, symposia, meetings and other events associated with NIH Scientific Meeting-NCCR2010.
Mark your calendar!!

Faculty comprises experienced practitioners from:
- IRB/IECs and Regulatory authorities
- Research administration & Funding bodies
- Investigators from NIH MOH and Universities
- NIH US and supporting research institutions from India, Hong Kong, Thailand, Singapore, Korea, Japan.
- Industry sponsors and CROs
# Collaborations: Private Hospitals

<table>
<thead>
<tr>
<th>#</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Prince Court Medical Centre</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.princecourt.com">www.princecourt.com</a></td>
</tr>
<tr>
<td>2</td>
<td>Sime Darby Medical Centre Subang Jaya (formerly known as Subang Jaya Medical Centre)</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.healthcare.simedarby.com">www.healthcare.simedarby.com</a></td>
</tr>
<tr>
<td>3</td>
<td>Sunway Medical Centre</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.sunway.com.my">www.sunway.com.my</a></td>
</tr>
<tr>
<td>4</td>
<td>KPJ Healthcare Group (18 Locations)</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.kpjhealth.com.my">www.kpjhealth.com.my</a></td>
</tr>
<tr>
<td>5</td>
<td>Pantai Group (9 Locations)</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.pantai.com.my">www.pantai.com.my</a></td>
</tr>
</tbody>
</table>
## Collaborations: Universities

<table>
<thead>
<tr>
<th>#</th>
<th>University</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>University Malaya Medical Centre (UMMC)</strong></td>
<td><a href="http://www.ummc.edu.my">www.ummc.edu.my</a></td>
</tr>
<tr>
<td>2</td>
<td><strong>Hospital University Sains Malaysia (HUSM)</strong></td>
<td><a href="http://www.usm.my">www.usm.my</a></td>
</tr>
<tr>
<td>3</td>
<td><strong>University Kebangsaan Malaysia Medical Centre</strong></td>
<td><a href="http://www.ppukm.ukm.my">www.ppukm.ukm.my</a></td>
</tr>
</tbody>
</table>
2. Develop Data Resources

Malaysian healthcare suffers from serious scarcity of healthcare data to inform policy & research

- How many Malaysian children visited their GPs for asthmatic wheeze in 2008? How are they treated?
- How many Malaysian women had mastectomy in 2006? How many went to get Herceptin? And how alive 5 years later?
- How many Malaysian men had heart attack in 2008? With what outcomes?
- etc

Two proven tools to produce the statistics:

- Patient registries
- Healthcare surveys

CRC
Research that matters to patients
Patient registry & Healthcare survey

These are organized information systems to collect, process, report and use both clinical service and individual patient level data for policy, clinical and research purposes.

Healthcare surveys target healthcare providers in Malaysia; while registry targets a specific patient population (defined by disease or therapy).

It employs survey methods to collect uniform data on clinical services in the country; and observational study methods to collect uniform patient level data to evaluate the treatment and health outcomes.
# Patient registers & Healthcare surveys supported by CRC

<table>
<thead>
<tr>
<th>#</th>
<th>Patient registries</th>
<th>Healthcare surveys</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>National Renal Registry</td>
<td>M’sian Cardio-Thoracic Registry</td>
</tr>
<tr>
<td></td>
<td>National Suicide Registry</td>
<td>Healthcare Establishment &amp; Workforce Survey</td>
</tr>
<tr>
<td></td>
<td>National Eye Database</td>
<td>National Medicines Use Survey</td>
</tr>
<tr>
<td></td>
<td>National Transplant Registry</td>
<td>Health professional registers</td>
</tr>
<tr>
<td></td>
<td>Nat. CVD (ACS/PCI) Database</td>
<td>National Neurology Registry</td>
</tr>
<tr>
<td></td>
<td>National Cancer Patient Registry</td>
<td>National Urology Registry</td>
</tr>
<tr>
<td></td>
<td>National Mental Health Registry</td>
<td>National Medical care Survey</td>
</tr>
<tr>
<td></td>
<td>Malaysian National Neonatal Registry</td>
<td>National Medical Device Survey</td>
</tr>
<tr>
<td></td>
<td>Hematological Malignancy Reg.</td>
<td>Post-Operative Mortality Review</td>
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<tr>
<td></td>
<td>National OT Register</td>
<td>National Nuclear Medicine Database</td>
</tr>
<tr>
<td></td>
<td>National Trauma Database</td>
<td>JPN National Death Register</td>
</tr>
<tr>
<td></td>
<td>Malaysian GI Registry</td>
<td>Maternal Mortality Register</td>
</tr>
<tr>
<td></td>
<td>National Mental Health Registry</td>
<td>National Paediatric Mortality Register</td>
</tr>
<tr>
<td></td>
<td>Nat. Inflammatory Arthritis Registry</td>
<td>Post-Operative Mortality Review</td>
</tr>
<tr>
<td></td>
<td>Nat. Orthopedic Reg Malaysia</td>
<td>Maternal Mortality Register</td>
</tr>
<tr>
<td></td>
<td>National Diabetes Registry of Malaysia</td>
<td>Maternal Mortality Register</td>
</tr>
<tr>
<td></td>
<td>Malaysian Registry of Intensive Care</td>
<td>Maternal Mortality Register</td>
</tr>
<tr>
<td></td>
<td>Nat. O&amp;G Patient Registry</td>
<td>Maternal Mortality Register</td>
</tr>
<tr>
<td></td>
<td>National Paediatric Mortality Registry</td>
<td>Maternal Mortality Register</td>
</tr>
</tbody>
</table>
Statistical Reports from Patient Registries
Healthcare Statistics
Drugs, Med. Technology, Health Service, Facilities & Workforce

<table>
<thead>
<tr>
<th>#</th>
<th>Healthcare Surveys</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>National Healthcare Establishment &amp; Workforce Surveys</td>
</tr>
<tr>
<td></td>
<td>(NHEWS) (NEW)</td>
</tr>
<tr>
<td>2</td>
<td>National Medical Care Survey</td>
</tr>
<tr>
<td></td>
<td>(NMCS) (NEW)</td>
</tr>
<tr>
<td>3</td>
<td>National Medicines Use Survey</td>
</tr>
<tr>
<td>4</td>
<td>National Medical Device Survey</td>
</tr>
</tbody>
</table>
The pharmaceutical, biotechnology, and medical-device industries must constantly discover and develop innovative therapeutic products (drugs or devices), and invest hugely in research & new product development.

Contract Clinical Research Industry has emerged over the last 20 years to serve the Pharma/Biotech industries by providing more efficient (*faster time to market*) and cost effective (*cheaper*) clinical development services. This is called Clinical Trial Outsourcing.

And increasingly Pharma/Biotech industries or their CROs are also *offshoring* clinical trials to emerging markets, including Asia.

“*Within two to three years, up to 65% of FDA regulated clinical trials for top pharmaceutical companies will be conducted abroad.*” Tufts Outlook 2007 Report, 3 January 2007
Asian CRO markets (Phase I–IV) earned revenues of $1.2 billion in 2006” Frost & Sullivan report Oct 2007
Eyeing M’sia for trials

Pharmaceutical firms view country as ideal location for research

By SIRA HABIBU
sira@thestar.com.my

KUALA LUMPUR: Pharmaceutical giants view Malaysia as an ideal location to carry out diagnostic and clinical trials for the global market.

Prime Minister Datuk Seri Najib Tun Razak said priority could be given to such value-added trials as Malaysia’s multi-ethnic composition represented a big portion of the global population.

“This also augurs well for Malaysia that aspires to be a successful global biotechnology hub,” he said, adding that the country had the competitive edge as it had the necessary resources.

Najib said this after chairing the 4th IAP meeting at the Kuala Lumpur Convention Centre here yesterday.

The Prime Minister also said a powerhouse research centre would be established in Malaysia to promote research and development.
Malaysia encourages global affiliations for the advancement of clinical research within the country and the region.

Malaysia has one of the most rapidly growing pharmaceutical markets in Asia Pacific ... reflects the Ministry of Health’s stand in recognising the critical role of this sector in the country’s healthcare system.

Dato' Seri Liow Tiong Lai
Minister of Health, Malaysia

Tan Sri Dato’ Seri Dr. Haji Mohd Ismail bin Merican
Director-General of Health, Malaysia
Malaysian government commitment to Contract Clinical Research

“ To drive industrialization to a higher level of global competitiveness….

… this is a critical endeavor for our national mission to attain developed nation status under Vision 2020”

Prime Minister Malaysia,

… Contract Clinical Research is a targeted industry in IMP3
As testimony to the government of Malaysia’s commitment to support clinical research, the NCCR is chaired by the MOH Director-General himself.

### Objectives:
- Infrastructure development,
- Training and Advisory on regulation of clinical research

### Activities:
- Dialogue with Industries and Investigators
- Survey on research infrastructure
- Guidelines drafting & implementation: Good Clinical Practice (GCP), Bioequivalence (BE), Good Lab Practice (GLP)
- Training on GCP/GLP
- Inspection of clinical trial sites to check compliance
- Review processes for application of clinical trials
- Regulatory guidelines: Application to Conduct Drug-Related CT, for Application For Clinical Trial Import License (CTIL)

As testimony to the government of Malaysia’s commitment to support clinical research, the NCCR is chaired by the MOH Director-General himself.
Guidelines and Legal Requirements

Guidelines:
- Malaysian Guidelines for GCP (Updated 2004)
- Guidelines for Application to Conduct Drug-Related Clinical Trials in Malaysia (2nd edition)
- Guidelines for Application of Clinical Trial Import License (CTIL) and Clinical Trial Exemption (CTX) in Malaysia
- National Institutes of Health (NIH) Guideline for Research conduct in MOH

Laws
- Control of Drugs and Cosmetics Regulation 1984
- The Poison Regulation (Psychotropic Substances) 1989
- Sale of Drugs Act 1952
What are our competitive strengths?

The Power Of Network

Modern Healthcare Infrastructure with state-of-the-art medical equipment

Experienced, GCP-Trained Investigators

English, the primary language

Reliable Oversight by a Centralised Institutional Review Board

Strong and Committed Government Support

Multi ethnic population
• A large pool of experienced, qualified and English literate Clinical Investigators

• Leading therapeutic areas:
  
  Cardiovascular, Diabetes, Oncology, Hepatology, Infectious disease, Psychiatry, Paediatric and Nephrology

  • Good Clinical Practice certification requirement

• Experienced trial sites familiar with requirements for effective patient recruitment and retention, reporting of clinical & AE data, Investigative Product (IP) accountability, and study documentation
### Number of Clinical Trial Applications by Therapeutic Class 2000-2008

<table>
<thead>
<tr>
<th>Therapeutic area</th>
<th>No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>DRUGS USED IN DIABETES</td>
<td>49</td>
</tr>
<tr>
<td>CARDIOVASCULAR SYSTEMS</td>
<td>40</td>
</tr>
<tr>
<td>CYTOTOXIC DRUGS</td>
<td>36</td>
</tr>
<tr>
<td>ANTIVIRAL DRUGS</td>
<td>33</td>
</tr>
<tr>
<td>DRUGS USE IN PSYCHOSES</td>
<td>27</td>
</tr>
<tr>
<td>ANAEMIAS &amp; OTHER BLOOD DISORDERS</td>
<td>24</td>
</tr>
<tr>
<td>ONCOLOGY DRUG</td>
<td>24</td>
</tr>
<tr>
<td>ANTIBACTERIAL DRUGS</td>
<td>19</td>
</tr>
<tr>
<td>RESPIRATORY SYSTEM</td>
<td>19</td>
</tr>
<tr>
<td>LIPID LOWERING DRUGS</td>
<td>14</td>
</tr>
<tr>
<td>DRUGS FOR GENITO-URINARY DISORDERS</td>
<td>12</td>
</tr>
<tr>
<td>GASTROINTESTINAL SYSTEMS</td>
<td>12</td>
</tr>
<tr>
<td>MUSCULOSKELETAL &amp; JOINT DISEASE</td>
<td>11</td>
</tr>
<tr>
<td>FOOD SUPPLEMENT/TRADITIONAL MEDICINE</td>
<td>10</td>
</tr>
<tr>
<td>DRUGS AFFECTING BONE METABOLISM</td>
<td>8</td>
</tr>
<tr>
<td>IMMUNOLOGICAL PRODUCTS &amp; VACCINES</td>
<td>8</td>
</tr>
</tbody>
</table>
Clinical Trials in Malaysia

*Source: Data of registered CT (1996-2006), National Pharmaceutical Control Bureau (NPCB) & 2007-2009, National Medical Research Register (NMRR)
## Breakdown of top 10 sponsors found in NMRR registration

<table>
<thead>
<tr>
<th>No</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Sanofi Aventis (2)</td>
<td>Sanofi Aventis (8)</td>
<td>Merck, Sharp &amp; Dohme (9)</td>
</tr>
<tr>
<td>2</td>
<td>Pfizer Inc (1)</td>
<td>Pfizer Inc (7)</td>
<td>Johnson&amp;Johnson (7)</td>
</tr>
<tr>
<td>3</td>
<td>Merck, Sharp &amp; Dohme (1)</td>
<td>Merck, Sharp &amp; Dohme (7)</td>
<td>Pfizer Inc (6)</td>
</tr>
<tr>
<td>4</td>
<td>Bristol-Myers (1)</td>
<td>Novartis (7)</td>
<td>Novartis (6)</td>
</tr>
<tr>
<td>5</td>
<td>La Jolla Pharmaceutical (1)</td>
<td>Boehringer Ingelheim (7)</td>
<td>Novo Nordisk Pharma (6)</td>
</tr>
<tr>
<td>6</td>
<td>Australian NHMRC (1)</td>
<td>Bayer AG (6)</td>
<td>Takeda Global Research (3)</td>
</tr>
<tr>
<td>7</td>
<td>Welcome Trust (1)</td>
<td>Johnson&amp;Johnson (6)</td>
<td>Roche (2)</td>
</tr>
<tr>
<td>8</td>
<td>Johnson&amp;Johnson (1)</td>
<td>Eli Lilly (5)</td>
<td>Otsuka Pharmaceutical (2)</td>
</tr>
<tr>
<td>9</td>
<td></td>
<td>Roche (5)</td>
<td>Sanofi Aventis (2)</td>
</tr>
<tr>
<td>10</td>
<td></td>
<td>Astrazeneca (4)</td>
<td>Astrazeneca (2)</td>
</tr>
</tbody>
</table>

*Note: NMRR started in year 2007 and all figure based NMRR registration.*
CROs in Malaysia

International CROs:

• Quintiles
• PAREXEL
• INC (formerly MDS)
• Covance
• Pharmanet
• PPDi
• The George Institute for International Health
• Novotech

Plus Four (4) locally incorporated CRO
Evolution of National Medical Research Register

(www.nmrr.gov.my)

Online system to support management of NIH research;
- Online research registration
- Online submission,
- Online review & approval of MOH research

Local Clinical trial registration: the registered research constitutes a database of ongoing and completed medical research projects in MOH;

NMRR set to become a National research database when it integrates the data from academia
The National Medical Research Register (NMRR) conforms with International Practice that all Clinical Trials should be registered with a public accessible database before enrollment of the first patient into any clinical trial.

ICMJE September 2004

Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors

World Medical Association Declaration of Helsinki 2008

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI
Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:

Director General of Health Malaysia Circular BIL. 9/2007

SURAT PEKERILING KPTUA PENGARAH KESIHATAN MALAYSIA BIL.9/2007
GARISPAUDUAN INSTITUT KESIHATAN NEGARA MENGENAI PENYELIDIKAN YANG DIJALANKAN DI INSTITUSI DAN FASILITI KEMENTERIAN KESIHATAN MALAYSIA
NMRR: Research Directory

Search Guidelines:
- By Investigator Name (Example: Tapping DEF - Will SEARCH and display ABC DEF GHI, and)
- By Title and Specialty and Sub-Speciality and General Area and Study Condition and Recruitment Status (Select ALL or choose from the drop-down list)

<table>
<thead>
<tr>
<th>No.</th>
<th>Research ID</th>
<th>Research Title</th>
<th>Research Type</th>
<th>Recruitment Status</th>
<th>Date Registered</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>161</td>
<td>An Observational Cohort Study to determine the long-term Safety and Efficacy of a Biogenic Epoietin (KeraFEG) treatment for renal anemia in patients with Chronic Kidney Disease</td>
<td>Clinical</td>
<td>Recruiting</td>
<td>18-07-2005 12:30PM</td>
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<tr>
<td>2</td>
<td>162</td>
<td>A 24-week prospective, multicentre, randomised, double-blind, placebo controlled study of DYSPORT® injection for the treatment of Upper limb spasticity in early stroke patients (Asian Botulinum Clinical Trial Designed for Early Stroke Spasticity)</td>
<td>Clinical</td>
<td>Recruiting</td>
<td>03-06-2005 08:29PM</td>
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<tr>
<td>3</td>
<td>188</td>
<td>EFFICACY OF SMTCTABIN IN COMBINATION WITH ORAL REHYDRATION IN THE TREATMENT OF ACUTE WATERY DIARRHEA IN INFANT AND CHILDREN A.PRESSURE (SMTABIN) controlled randomized, double-blind, parallel groups, multicenter study</td>
<td>Clinical</td>
<td>Recruiting</td>
<td>09-05-2008 11:29PM</td>
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<td>4</td>
<td>664</td>
<td>THE EFFECTIVENESS OF EPIDURAL 0.5% LEVOpropine WITH CLONIDINE OR FENTANYL IN LOWER LIMB SURGERY</td>
<td>Clinical</td>
<td>Recruiting</td>
<td>18-07-2007 12:02PM</td>
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<td>5</td>
<td>803</td>
<td>An open labelled, multicentre, randomised placebo controlled study of combination Gemcitabine and Carboplatin chemotherapy in patients with metastatic or recurrent Non-Small-Cell Lung Carcinoma</td>
<td>Clinical</td>
<td>Recruiting</td>
<td>18-09-2007 18:09PM</td>
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<td>6</td>
<td>1089</td>
<td>Clinical Study (D 118) A double-blind, randomised, parallel-group, placebo-controlled study of the safety, tolerability and efficacy following sequential dose regimen of Lu 371-108 in patients with schizophrenia</td>
<td>Clinical</td>
<td>Recruiting</td>
<td>17-12-2007 14:52PM</td>
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<td>7</td>
<td>1091</td>
<td>Comparison of two different intensive insulin therapy protocols in intensive care</td>
<td>Clinical</td>
<td>Recruiting</td>
<td>17-12-2007 19:14PM</td>
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<td>8</td>
<td>1209</td>
<td>Transplant (Telematic Randomised Assessment Study in ACE Intolerant Subjects with Cardiovascular Disease) Study</td>
<td>Clinical</td>
<td>Recruiting</td>
<td>07-01-2008 14:41PM</td>
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<td>9</td>
<td>1211</td>
<td>Stamplotin versus glipizide in patients with end stage renal disease who are on hemodialysis</td>
<td>Clinical</td>
<td>Recruiting</td>
<td>07-01-2008 15:19PM</td>
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<td>10</td>
<td>1215</td>
<td>A cross over study to evaluate the lipid altering efficacy of MK-0524B combination tablet compared to MK-0524A and alone in administration in patients with primary Hypertriglyceridaemia &amp; mixed hyperlipidaemia</td>
<td>Clinical</td>
<td>Recruiting</td>
<td>07-01-2008 16:47PM</td>
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</table>
Audit & Regulatory Inspection

Malaysia’s favorable experience with sponsor’s audit and regulatory inspection

Sponsor pre-qualification or on-study audit
- Pfizer, Sanofi-Aventis, B Braun, Beaufour Ipsen, Mitsubishi Pharma, etc etc

Regulatory inspection
- European Medicines Agency (EMEA)
- Food and Drug Administration (FDA)
Asian Clinical Trial Network: partners in Korea, Taiwan and Vietnam

Other partners in Asia: Singapore, Thailand, Philippines, and Australia

Aga Khan University Pakistan

International Clinical Epidemiology Network (INCLEN)
4. Investigator Initiated Research (IIR/ IIT)

Original clinical research work initiated and conducted by Malaysian investigators to:

- Fill critical knowledge gap relevant to Malaysian public health
- Enhance Malaysia’s contribution to the clinical evidence base, especially in disease & therapy areas relevant to our population’s health
### CRC Research Publication Output

<table>
<thead>
<tr>
<th>Year</th>
<th># journal publications</th>
<th># publications in JIF&gt;1</th>
<th># research or registry reports</th>
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<tbody>
<tr>
<td>2002</td>
<td>4</td>
<td>4</td>
<td>0</td>
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<tr>
<td>2006</td>
<td>16</td>
<td>11 (69%)</td>
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</tr>
<tr>
<td>2007</td>
<td>18</td>
<td>11 (69%)</td>
<td>2</td>
</tr>
<tr>
<td>2008</td>
<td>42</td>
<td>12 (28%)</td>
<td>14</td>
</tr>
<tr>
<td>2009</td>
<td>49</td>
<td>19 (37%)</td>
<td>13</td>
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</table>

Type of investigations ranged from case reports, clinical trials, healthcare quality, health outcomes, clinical epidemiology & health economics.
MOVING FORWARD
Where do we go from here?

- **Contract research**: Corporatized under RM10, incentive for MOH health professionals, but need to strengthen human subject protection
- **Data resources**: Need assured funding support, better access to available data sources, strengthen IT and statistical capabilities
- **Investigator initiated research**: More original work, better supported investigators, more competitive grant awards
Strategic Plans

Four key actions under RM10

1. Corporatized Entity (100% govt owned; like Health Tourism Council, Health promotion board) to manage contract research: Marketing & business development, hire & retain industry talents, partner commercial CROs/SMOs etc

2. Increase required human capital

3. Incentivize MOH health professionals (doctors, pharmacists, nurses etc.)

4. Human subject protection: Stringent and independent review & ongoing oversight
Proposal: build strong capabilities housed within an optimal framework

Clinical research ecosystem: strengthening the pillars within a supportive framework ...

...to drive key success factors ...

...that create positive outcomes

1. Governance
2. Scope of trials
   - Human capital
   - Process
   - Resource
3. Organisation
4. Research culture

Social and economic impact
- Patient access
- Innovation capabilities
- Physician capabilities
- Publications and reputation

Speed + Quality

Proposals: build strong capabilities housed within an optimal framework.
Case Study: Refining Clinical Research Infrastructure

Featuring:
- Malaysian Healthcare and Clinical Research Infrastructure
- Industry-Sponsored Clinical Trials in Malaysia
- Refining Clinical Research Infrastructure in Malaysia

Clinical Trial Magnifier
Jun 2010
Volume 3, Issue 3
Pg 203-218
http://www.clinicaltrialmagnifier.com/archive.aspx
Grow Malaysia's Clinical Research Ecosystem

- Facilitate bioavailability & bioequivalence development
- Expand scope of trials: Early Phases, Stem Cell, traditional Genomics
- Increase sites: MOH/ Uni/ Private
- Grow pool of investigators, site coordinators
- Tap larger pool of patients
- Optimise ethics and regulatory processes
- Attract more international and local sponsors
- Grow number of contract research org and improve site management
- Transform MOH's One-Stop Centre into a business entity
- Build Malaysia's reputation as clinical trial hub

Clinical Trials 800 / yr
Further Strengthening of Research collaboration

1. Network of CRCs in Malaysia: MOH + University + Private sectors
2. Cooperative Clinical Research Groups (CRG)
3. Public-Private partnership: engaging private sector partners
4. Biotech Corp & MIDA: Working with other government agencies with overlapping responsibility
5. International linkages
KIV: : Malaysia Clinical Trial Act 2020 ?
Thank You

www.crc.gov.my