Paediatric Clinical Trials in Malaysia

By
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Ministry of Health Malaysia
Introduction

- Clinical trials in Malaysia
- Clinical Research Centres in Malaysia
- National Committee for Clinical Research (NCCR)
- Regulatory Aspects
- National Medical Research Register
- Paediatric Clinical Trials in Malaysia
Number of Clinical Trials Conducted in Malaysia (2000–2009)

(excluding Bioequivalence Studies)

*Note:
1. Statistics are based on the number of applications received by National Pharmaceutical Control Bureau for the clinical trial import license for unregistered products.
2. Drug-related clinical trials for registered products which do not require clinical trial import license is not controlled by the Drug Control Authority.
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No. of CTs Conducted by Therapeutic Class* (2003-2009)

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Commitment to boost 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”

... Contract Research is a targeted industry
ECONOMIC TRANSFORMATION PROGRAMME 2010– Clinical Research Centres

- Transform the industry by creating a supportive and complete ecosystem
- Build on speed & quality
- Promote centres of excellence
- Create a one-stop centre as a business entity
- Build on the strengths of integrated network and information system
- Galvanise local investigators
Clinical Research in Malaysia

1. Strong commitment & support for the contract research industry and Sponsors

2. Conducive Clinical Research environment:
   - Qualified and well trained medical professionals working in modern medical facilities
   - Large patient population, especially diabetes, cancer, heart diseases and hepatitis
   - Diverse culture/multi-ethnic population
   - Low cost advantage
   - Efficient logistics for trial supplies & biospecimen
Clinical Research in Malaysia

3. Regulatory System in place

- Enforcement of compliance with GCP/ GLP
- IPR protection regime
- Timelines for ethics review & regulatory approval (CTIL/CTX)
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
National Committee for Clinical Research (NCCR)

NCCR is made up of representatives from the

- Ministry of Health
- Various National Universities
- Malaysian Pharmaceutical Society
- Pharmaceutical Association of Malaysia
- Malaysian Organisation of Pharmaceutical Industries
- Other Non-Governmental Organisations.

www.nccr.gov.my
National Committee for Clinical Research (NCCR)

Some of NCCR’s objectives

- Establish policies and plan clinical trial activities in Malaysia.
- Utilize all experts available in the Ministry of Health Malaysia, academia and pharmaceutical industries.
- Take pro-active action at all times in enhancing clinical research

www.nccr.gov.my
Regulatory Aspect
Clinical Trial Approvals

- Application to Medical Research Ethics Committee

- Application for Clinical Trial Import License (CTIL) to import unregistered product for clinical trial purpose and Clinical Trial Exemption (CTX) to manufacture unregistered product for clinical trials
Guidelines

1. Malaysian Guidelines for GCP
   - Updated 2004
   - Available in NPCB website

2. Guidelines for the Application of CTIL and CTX in Malaysia
   - Updated June 2009
   - Available in NPCB website

3. Guidelines for Good Clinical Practice Inspection 1st Edition
   - October 2010
   - Available in NPCB website
<table>
<thead>
<tr>
<th>Institution</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC, MOH</td>
<td>6 – 8 weeks</td>
</tr>
<tr>
<td>IEC, Universities</td>
<td>4 – 8 weeks</td>
</tr>
<tr>
<td>IEC, National Heart Institute</td>
<td>3 – 6 weeks</td>
</tr>
<tr>
<td>DCA</td>
<td>30 working days*</td>
</tr>
</tbody>
</table>
Other guidelines for clinical research in Malaysia

1. Guidelines for the conduct of bioavailability & bioequivalence studies, Sept 2000

2. Guideline on the Use of Human Biological Tissues for Research

3. Guidelines for Ethical Review of Research involving human subjects
GCP workshops in Malaysia

Each year about 350 investigators are trained and certified in ongoing GCP training workshops.
Registration of Independent Ethics Committee with DCA

- All Independent Ethics Committee approving drug related trial must be registered with the Drug Control Authority

- This directives was issued under Regulation 29, Control of Drugs and Cosmetics Regulations 1984 (Revised 2006)
National Medical Research Register

- Online system to support management of NIH research;
  - Online research registration
  - Online submission
  - Online review and approval of MOH research
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# Paediatric CT in Malaysia

<table>
<thead>
<tr>
<th>Year</th>
<th>No of CT</th>
<th>Title</th>
<th>No of Sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>2</td>
<td>A prospective Randomized, Double Blind, Placebo-Controlled Trial to Determine the Safety and efficacy of influenza Virus Vaccine, Trivalent, Types A &amp; B, Live Cold-Adapted (CAIV-T) in Healthy Children.</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Open, randomised study to evaluate the immunogenicity, safety and reactogenicity of two different immunization regimens against hepatitis B, diphtheria, tetanus, pertussis and H. influenzae type b(Hib) diseases in healthy infants primed with a birth dose of GSk Biologicals’ hepatitis B.</td>
<td>2</td>
</tr>
<tr>
<td>2001</td>
<td>2</td>
<td>A prospective, multicenter, double-blind, randomized, comparative study to evaluate the safety, local tolerability, and clinical outcome of Ertapenem sodium(Mk-0826) Vs Ceftriaxone Sodium in Paed. Px with complicated UTI, Skin &amp; Soft Tissue Infection, or community acquired pneumonia.</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>A 24-week randomized, double-blind, active-controlled, multicenter study to evaluate the safety &amp; efficacy of rosiglitazone when administered to pediatric patients with Type 2 diabetes mellitus.</td>
<td>3</td>
</tr>
<tr>
<td>2002</td>
<td>0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2003</td>
<td>1</td>
<td>A randomized, double-blind, placebo controlled, dose ranging, parallel group study of Oral Sildenafil in the treatment of Children, Aged 1-16 years, with Pulmonary Arterial Hypertension (phase 2/3)</td>
<td>1</td>
</tr>
<tr>
<td>2004</td>
<td>0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2005</td>
<td>0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2006</td>
<td>1</td>
<td>Efficacy of SMECTA in combination with oral rehydration in the treatment of acute watery diarrhea in infants and children.</td>
<td>12</td>
</tr>
<tr>
<td>Year</td>
<td>No of CT</td>
<td>Title</td>
<td>No of Sites</td>
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<tr>
<td>2007</td>
<td>4</td>
<td>International randomized, double-blind clinical study evaluating the efficacy and safety of clopidogrel 0.2mg/kg once daily versus placebo in neonates and infants with cyanotic congenital heart disease palliated with a systemic-to-pulmonary artery shunt (e.g. modified Blalock Taussig Shunt).</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 months, multicenter, double-blind, randomized, placebo-controlled, parallel-group study to investigate the efficacy of two doses of alfuzosin (0.1mg/kg/day; 0.2 mg/kg/day) in the treatment of children and adolescents 2-16 years of age with elevated detrusor leak point pressure of neuropathic etiology followed by a 40 weeks open label extension study</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>12 weeks, multicenter, open-label study to investigate pharmacodynamic and safety of alfuzosin 0.2 mg/kg/day in the treatment of children and adolescents 2-16 years of age with hydronephrosis associated with elevated detrusor leak point pressure of neuropathic etiology followed by a 40 weeks open label extension study</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>International randomized study to evaluate the addition of docetaxel to the combination of cisplatin-5-fluorouracil (TCF) vs. cisplatin-5-fluorouracil (CF) in the induction treatment of nasopharyngeal carcinoma (NPC) in children and adolescents</td>
<td>2</td>
</tr>
<tr>
<td>2008</td>
<td>1</td>
<td>A phase IIIb, single group, open study, to assess the immunogenicity, safety and reactogenicity of GSK Biologicals’ 10-valent pneumococcal conjugate vaccine, co-administered with Biologicals’ DTPa (Diphtheria-tetanus-acellular pertussis) -combined vaccines and GSK Biologicals’ Rotarix during the first 6 months of age</td>
<td>2</td>
</tr>
<tr>
<td>2009</td>
<td>1</td>
<td>Safety and immunogenicity of the Japanese Encephalitis (JE) vaccine IC51 (Ixiaro®) in a Pediatric Population. Open-Label, randomized, active controlled phase 3 study</td>
<td>2</td>
</tr>
</tbody>
</table>
Issues Paediatric Clinical Trials

- Subject recruitment
- Practical problems with informed consent
- Trial design
- Insurance
- Influence/Undue Inducement
- Ethical issues
Current Plans and Activities

- Studies to explore the need for new legislation
- Review of procedures, management of finances
- Protection Intellectual Property Rights
- Using ICT to increase efficiency in conducting clinical trials
- Creating database of clinical investigators and research done in Malaysia through National Medical Research Register (NMRR)
- Carrying out more awareness and education programmes.
Thank you