




Clinical Research and Early Childhood Intervention:
The Importance of Research and Translating Research into Policy and Practices


Amar-Singh HSS (Dato' Dr)
 Cert Theology (Aust, Hons), MBBS(Mal), MRCP(UK),
 FRCP(Glasg), MSc Community Paeds (Lond)
 Head Clinical Research Center Perak
 Senior Consultant Paediatrician (Community)
 Head Paediatric Department, Hospital RPB Ipoh, Perak
 President NECIC

<http://www.crc.gov.my>

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Overview

1. Introduction to research
2. Introduction to Clinical Research Centre (CRC)
3. NKEA (Healthcare) targets & Clinical Research Malaysia (CRM)
4. Why do we require research/clinical trials in children?
5. Research in the area of Early Childhood Intervention (ECI)



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Introduction to research

1. Research is the systematic investigation into existing or new knowledge.
2. Used to establish or confirm facts and solve new or existing problems

A mechanism to establish “what works”
 As opposed to opinion or experience based treatment
 (example)



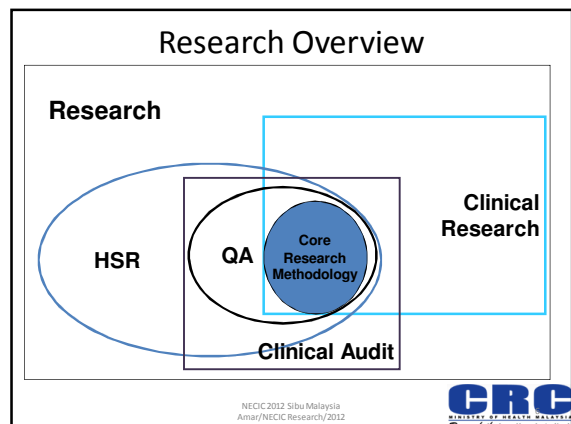
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Introduction to research

1. Long history of research activities and initiatives in Malaysia
2. Less so in the disability scene
3. Clinical research largely conducted by medical doctors and allied health professionals




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How have we Benefitted from Research?

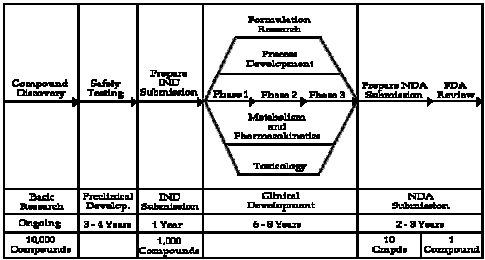
Examples

- ☉ Childhood vaccines
 - NB: Current vaccines in development (Dengue)
- ☉ All the medications we use
- ☉ Many of the programmes that are conducted in health (e.g. screening for diseases)



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New drug development

During new drug development, a critical phase is the clinical development phase when the new molecular entity (NME) undergoes testing in human to demonstrate safety & efficacy.



Compound Discovery	Safety Testing	Preclinical Development	IND Substitution	Phase 1	Phase 2	Phase 3	Preparatory NDA Substitution	FDA Review
				Formulation Research Preformulation Development Metabolism and Pharmacokinetics Toxicology				
Basic Research	Preclinical Development	IND Substitution	Clinical Development			NDA Substitution		
Ongoing	3 - 4 Years	1 Year	6 - 8 Years			2 - 3 Years		
10,000 Compounds		1,000 Compounds				10 Changes 1 Compound		


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What must be there before we do research?


- ☉ Social Value
 - it contribute to well-being of society in general
- ☉ Scientific Merit
 - that medical research involving human subjects must be justifiable on scientific grounds
- ☉ Risks and Benefits
 - demonstrate that risks to research subjects are not unreasonable or disproportionate to expected benefits of research


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The Ethical Struggle in Research

“The **primary ethical struggle** in clinical research, therefore, is **that a few individuals are asked to accept burden or risk as research subjects in order to benefit others and society.....**”

Christine Grady in “Principles & Practice of Clinical Research”


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What Research Do We Need?

The 10/90 gap in medical research

- ☉ “The major problems facing research today is the lack of application of research findings. Conducting research for ‘research sake’ or the ‘publish or perish mentality’, has resulted in a flood of research publications that have little impact on health – the **10/90 gap in medical research (only 10% of global research funding is spent on health problems that affect 90% of the world’s population)**. What is required today is applied research – research that impacts the health of the individual and the community, resulting in meaningful improvement in health status.

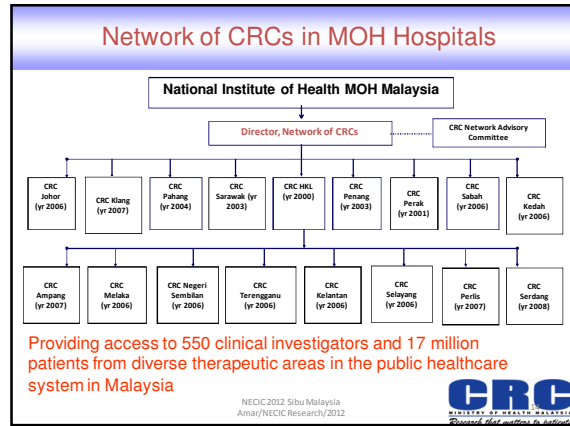
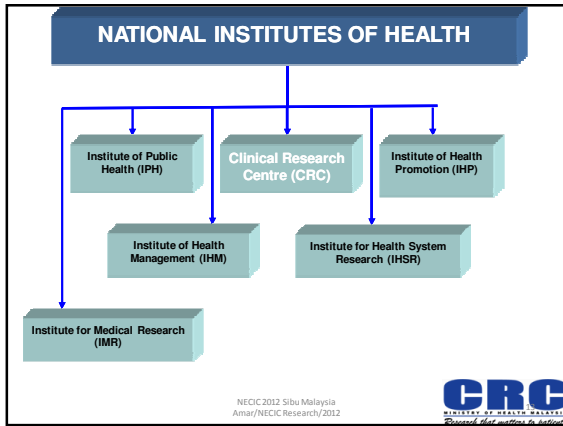
Amar-Singh HSS, Azman Abu Bakar, Sondi Sararaks.
The Medical Research Handbook, 2012 (2nd edition)

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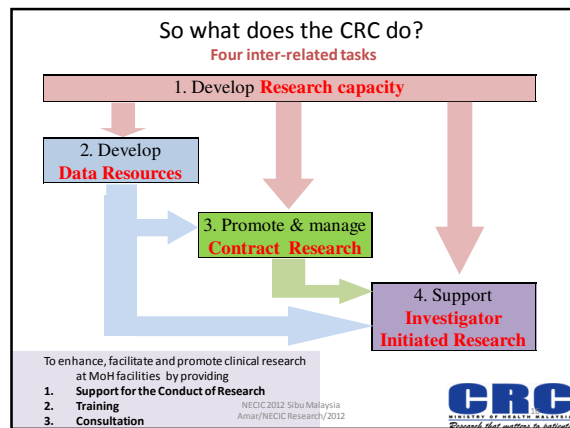
CRC's vision & dual missions

For the people's health & wealth

CRC is **both** a MOH and Govt organization

- 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
[Investigator initiated Research]
- As a **Government Research institute**, we also share responsibility for Malaysia's critical national mission - To be a high income country by 2020
Specifically, to contribute to the development of Malaysia as clinical research hub for the clinical research outsourcing industry"
Contract research mission for the people's wealth

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NKEA: Healthcare Clinical Research Malaysia

Creating a supportive environment and complete ecosystem to grow number of trials. Target 1,000 new trials by 2020.

- The global contract research in Asia has outpaced the global market with annual ~30% growth
- Malaysia's performance has lagged behind its Asian peers
- Transform the industry by creating a supportive and complete ecosystem to grow # of new trials by building reputation for speed and quality, promoting COEs and by building on MOH's integrated network and info system.

RM 578.4 million	1000
GNI Impact	Jobs Created

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Malaysia's Competitive strength

Economic Transformation Programme, RM 10
EPP 2: Clinical Research Malaysia (CRM)
 Malaysia being a multiracial nation offers the perfect environment for drug research and clinical trials. Business opportunities in this sector are abundant. The Government is working hard to convert CRM into an autonomous business entity in order to coordinate CRM activities more efficiently.
 Target of growing our current performance of 100 trials per year to 800

Clinical Research Malaysia (a new corporatized business entity under MOH)
 CRM that will market directly to **international pharmaceutical companies** to run their drug trials in Malaysia.



Research Focus/Mechanism

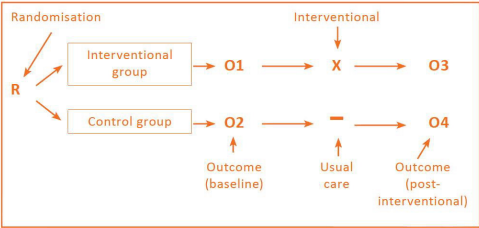
- ⊙ Industry led Clinical Trial
- ⊙ Investigator initiated Clinical Trial


- ⊙ Clinical Trail vs Community trials
- ⊙ Clinical Trail vs non-clinical trials



Clinical Trials


Figure 5: Randomised control trial (RCT)






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Why perform clinical trials in children?

- Children are a unique population
- Distinct developmental and physiological differences from adults
- Many medications given to children are off-label (ie, prescribed for children despite being approved only for adults), uncensored for use in children, and without adequate pharmacokinetic or safety data regarding use in children



Why perform clinical trials in children?

- Many prescribed treatments for children have **not been adequately tested in children**, sometimes resulting in harmful treatments being given and beneficial treatments being withheld
- Clinical trials in children are essential to develop age-specific, empirically-verified therapies and interventions to determine and improve the best medical treatment available



Problems with Clinical Trails in Children



Clinical Trials in Children

- Children eligible for trials limited because many conditions uncommon in children
- Harder to get consent & more complex because parents have to make decisions
- Parents and paediatricians generally opt for the new intervention or for standard care rather than trial participation

Clinical trials in children. Caldwell, et al, Lancet 2004


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Research & Early Childhood Intervention

- Internationally research ECI area growing
- Parents instrumental in initiating research via foundations (example)
- Studies published, used to improve care for children with disability and help pressure for critical services
- Need to early childhood intervention in Malaysia into mainstream of research in ECI

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Early Childhood Interventions

Proven Results, Future Promise

Lynn A. Karoly
M. Rebecca Kilburn, Jill S. Cannon

Prepared for
The FNC Financial Services Group, Inc.

LABOR AND POPULATION


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Research & Early Childhood Intervention Needs in Malaysia

- Need to use available research in ECI
- Need to audit existing services providing ECI
- Need to audit existing ECI programmes
- Need to identify the areas that require research (unique to local context)


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Research & Early Childhood Intervention Way Forward in Malaysia

- Bring reliable research methodology into ECI area
- Encourage peer review publication
- Have increased parental & NGO involvement
- Easily accessible database of studies conducted to facilitate learning and prevent duplication

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Research & Early Childhood Intervention Way Forward in Malaysia

- Encourage the use of research to seriously evaluate all policies and programmes for children with disability, inclusive of services run by government, NGOs and private professionals
- We need individual champions, both parents and professionals, to chart the way for us to follow

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6. How you can help – a survey

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Survey on Possible Involvement in Research

1. A survey to understand the public general understanding about clinical trials in Malaysia
2. and willingness to participate in clinical trials
3. It requires < 15 minutes to answer (4 pages)
4. Approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia.

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