DATE : 9-10 JULY 2009 | VENUE : G HOTEL, PENANG

SECOND ANNOUNCEMENT

NCCR 09
NATIONAL CONFERENCE FOR CLINICAL RESEARCH

A premier annual event which attracts

- Investigators, researchers & scientists
- Sponsors & industry experts
- Institutional Review Board Members
- Regulators & policy makers
- Other professionals involved in clinical research in MALAYSIA

An opportunity to

- Build bridges across clinical specialties & research areas
- Seek better research options to develop new ventures
- Discover, discuss & disseminate clinical research information
- Be part of a multidisciplinary community, promoting clinical research in the Asia Pacific region

Expanding the range of clinical research in Malaysia

Comprehensive program & exciting range of pre-conference workshops & seminars on Contract research industry, Clinical trials in variety of therapy areas, Research ethics & regulations, Drug development, Pharmaceutical medicine and Health economics

Track: Keynote & Plenary	
Keynote address: Clinical research in Malaysia	Tan Sri Dato' Seri Hj Dr Mohd Ismail Merican Director-General of Health Malaysia
Plenary: Regulations & MOH guidelines for clinical research	Dato' Dr Maimunah A Hamid Deputy Director- General of Health (R&TS) MOH
Plenary: Globalization of Clinical Trials - Trends, Effects and Significances	Prof Johan P.E. Karlberg Director, Clinical Trials Centre The University of Hong Kong
Plenary: Pharmaceutical Medicine	Dr Jean-Paul Deslypere SGS Life Science Services-Clinical Research
Track: Clinical research in Malaysia	
The MOH Research Ethics Committee	Dato' Dr Chang Kian Meng Chair, Medical Research Ethics Committee
Funding for clinical research in financially challenging times	Dr S. Asmaliza Ismail Head, NIH Secretariat, MOH/MREC
NPCB as a GLP Compliance Monitoring Authority for Malaysia	Dr Kamaruzaman Saleh Head of Clinical Research & Compliance Section, National Pharmaceutical Control Bureau, MOH
Role of CIC in promoting clinical research in UMMC	Prof Dr Rosmawati Mohamed, University Malaya Medical Centre UMMC
Role of CRC in promoting clinical research in HUSM	Prof Dr Nor Hayati Othman Dean (Clinical Research Platform) Universiti Sains Malaysia
Role of CRC in promoting clinical research in UKMMC	Prof Dr Rohaizak Muhammad Deputy Dean of Research and Industry University Kebangsaan Malaysia Medical Centre UKMMC, Chair UKM ethics committee
Conducting clinical trial in Malaysia: Pharma sponsors' experience	Dr Bernard Ng Medical Director, Sanofi-aventis
Track: CRO industry in Malaysia	
Role of CRC in promoting Malaysia to industry	Dr Ong Loke Meng Head of CRC Hospital Pulau Pinang
Development of the CRO industry in Malaysia	Mr Selvam Ramaraj Senior VP Healthcare, BiotechCorp Malaysia
Clinical Research Outsourcing: Opportunities and challenges	Dr Anand Tharmaratnam CEO Quintiles SE Asia
Track: Drug development	
Cancer genomics, biomarkers & drug development	Dr Teo Soo-Hwang Chief Executive, Cancer Research Initiatives Foundation, CARIF
Virtual drug development	Dr Christo van Niekerk CEO Global Alliance for TB Drug Development
Early phase studies: Does Malaysia have a chance?	Dr Maurice Cross Director, Veeda Clinical Research UK
International GLP standards	Dr Kumar Kurumaddali Malladi India
Tissue banking & drug development	Dr Matthew Lear Director of Strategic Alliances, Asterand US
Track: Off the beaten path	
Breast cancer research	Prof Dr Yip Cheng Har Consultant in General and Breast Surgery, UMMC
Paediatric clinical trial in Malaysia	Dato' Dr Jimmy Lee Kok Foo Head of CRC Terengganu
Medical device epidemiology & Malaysian statistics on medical device	Mr. Zamane Abdul Rahman Director Medical Device Bureau MOH Chairman NMDS

**Organizer reserves the right to amend programme without liability*

CO-ORGANISED BY: acrpm CRiSP

www.acrpm.com.my

SUPPORTED BY: CRC MINISTRY OF HEALTH MALAYSIA Research that matters to patients

www.crc.gov.my

PRE-CONFERENCE COURSES, SEMINARS & SYMPOSIA

New Early Clinical Development Symposium*

- **Date: 6 July 2009**
- **1-day symposium**
- **Registration fees: RM600 (USD350)**

Malaysia is developing its early phase clinical development capability. A seminar on this topic is most welcome to raise awareness on many of the issues and challenges in this new initiative. And we are grateful to the various experts including clinical pharmacologists from industry who has agreed to help put his event together.

Topics shall include:

Early drug development

- Overview of early drug development and decision paths .
- Translational Medicine as a discipline
- The First-into-Human study, and what did Te-Genero teach us?
- Regulatory Approval for early clinical development studies
- Setting up a Phase 1 Unit: What it takes? And what sponsors look for?
- Healthy volunteers & patient-volunteers, the value of different populations

Cardiovascular safety in drug evaluation

- The long QT syndromes, an interesting history of a recent awareness
- Pre-clinical evaluation of drug candidates
- Evaluating cardiovascular drug toxicity in early clinical development
- The FDA approach to QTc evaluation and implications for drug development
- Techniques to monitor cardiovascular drug safety in the Phase I Unit

Limited to 50 participants only. REGISTER NOW!

New Advanced Good Clinical Practice Workshop*

- **Date: 7-8 July 2009**
- **1 ½ day course**
- **Registration fees: RM800 (USD450)**

This course provides a detailed understanding of the latest developments and requirements of ICH GCP, and gives practical advice.

By the end of this course, you will understand:

- Diverse GCP concepts relevant to sites and monitors
- Compliance with consent requirements
- Management of monitoring and audit
- Resolution of ethical challenges
- Concepts of pharmacovigilance
- Preparation of research publications

Each theme will cover a brief presentation and case studies

Limited to 50 participants only. REGISTER NOW!

CRC's Good Clinical Practice Workshop*

- **Date: 6-8 July 2009**
- **2 ½-days course**
- **Registration fees: RM800 (USD450)**

GCP is the international quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials. Compliance with GCP provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial subjects are protected.

Malaysia adopted GCP in 1999, and since then doctors are required to undergo training on GCP leading to certification prior to participation in clinical trials. This highly popular course is specifically designed to meet this requirement.

Limited to 60 participants only. REGISTER NOW!

New Clinical Trial Management Workshop*

- **Date: 7-8 July 2009**
- **2-day course**
- **Registration fees: RM650 (USD400)**

This course is designed for site coordinators/study nurses, clinical professionals, CRAs or any other professionals who aspires to be clinical research professionals managing clinical trial at research sites. It provides the practical approach on how to manage a clinical research site professionally.

Topics shall include :

- Pre-study Management
  - Roles & Responsibilities of Site Coordinator
  - Prepare for Sponsor's pre-study visit
  - Laboratory issues
  - Study Initiation
- Study Execution
- Audit

Limited to 50 participants only. REGISTER NOW!

Other planned events, Mark your calendar please:

#	Date	Workshop/ Seminar/ Event
1.	8 July (5-7pm)	AGM ACRP Malaysian Chapter
2.	9 July 5-7pm	Mid-year Dialogue with Investigators and Industry sponsors for clinical trial
3.	To be announced	Pharmaceutical Medicine seminar: Plants to Medicines
4.	To be announced	Drugs for Neglected diseases

PRE-CONFERENCE COURSES, SEMINARS & SYMPOSIA

Health & Pharmaco-economics Workshop*

- **Date: 7 July 2009**
- **1-day workshop**
- **Registration fees: RM450 (USD250)**

This course is designed for clinicians and managers to achieve a basic understanding of health economics, in particular the concept of cost effectiveness as means to describe the comparative value of a health care product or service in terms of its ability to achieve a desired health outcome for a given unit of resources.

Topics that will be covered include:

- Health outcome assessment: Quantity & Quality of Life, Utility & QALYs
- Resource use & costing
- Measure of cost-effectiveness
- Pharmaco-economic evaluation of a new drug and medical device
- Economic evaluation of a healthcare program

Limited to 50 participants only. REGISTER NOW!

Research, Publications & Citations*

- **Date: 7 July 2009**
- **1-day seminar**
- **Registration fees: RM450 (USD250)**

This workshop discusses the significance of research and publications as indicators of knowledge production. It explains the important link between publications and citations which are now used to indicate the quality and international recognition of the published knowledge. In the modern era of information explosion, scientists and researchers should be aware of strategies in obtaining the right information from the right information provider so as to ensure they have the good start in research and publications that will lead to citations and recognition.

Target audience:

Clinical investigators and Researchers, Research supervisors, Research funders & administrators, Policymakers, University Librarians, Managers of Information Services, Journal Editors and Reviewers, Editorial Board members of journals,

Key topics:

- Research, Publications and Citations
- The ISI Journal Selection Process, Impact Factors and the Journal Citation Report on the ISI Web of Knowledge
- Web of Science, EndNote, Researcher ID
- Investigator Portal and Translational Research
- Publication ethics

Limited to 50 participants only. REGISTER NOW!

Healthcare Economics Workshop*

- **Date: 8 July 2009**
- **1-day workshop**
- **Registration fees: RM600 (USD350)**

Another introductory course designed for payers, managers & providers on healthcare economics, which is concerned with informing healthcare policy on expenditure & financing, health service provision and distribution to achieve healthcare quality, efficiency & equity goals.

Course Contents

Topics shall include:

- Healthcare expenditures & healthcare financing (Tax funding, health & social insurance, Employer's benefits, OOP)
- MOH healthcare budget, service delivery and scope for private sector participation in service provision & contracting
- Health manpower needs & projection
- Expenditures on and utilization of medicines & medical technologies
- Financing & healthcare equity
- Healthcare efficiency: Trading off quality?
- Healthcare quality: Trading off efficiency?
- Public-private roles in healthcare
- Healthcare regulation: Quality at what cost?

Limited to 50 participants only. REGISTER NOW!

Continuing Education on Research Ethics cum Forum for Ethics Review Committees in Malaysia (FERCIM)*

- **Date: 8 July 2009**
- **1-day event**
- **Registration fees: RM100 (USD50)**
- **Sponsor: CRC MOH**

This year, we are taking the opportunity to initiate Continuing Education on Research Ethics in the morning, to be followed by the annual Forum for Ethics Review Committees in Malaysia (FERCIM), in the afternoon.

We have invited an experienced faculty to present on:

- Best practices for IRB/IECs:
  Constitutions, SOPs development, Role of a dedicated professional IRB administrator, Training for IRB members, Accreditation of IRB/IEC
- Challenges for Ethics committees in Malaysia
- The Helsinki Declaration revisited:
  What's new in the Oct 2008 revision?
- Research misconduct:
  Fraud, Conflict of interest, Publication ethics & Clinical trial registration
- What's new in Informed Consent:
  Concept of assent, Special situations (Legally incompetent, Illiterate or subjects who are unable to read, Non-therapeutic trial, Emergency situation, Vulnerable subjects), Waiver of informed consent

Limited to 55 participants only. REGISTER NOW!

ANNOUNCEMENT

NCCR 09 SCIENTIFIC POSTER COMPETITION.
ENTRIES ARE NOW OPEN, FOR INSTRUCTIONS AND SUBMISSIONS PLEASE CONTACT:

Ms Nurul Huda
Tel : 603-26980310
Email: nurulhuda@crc.gov.my

Ms Balqissiah
Tel : 604-7407391
Email: balqissiah@crc.gov.my

Registration

Name 1:			
Position 1:		**H/P 1:**	
Email 1:			
Name 2:			
Position 2:		**H/P 2:**	
Email 2:			
Name 3:			
Position 3:		**H/P 3:**	
Email 3:			
Organization:			
Mailing Address:			
Contact Person:		**Email:**	
Tel (office):		**Fax:**	

Events	Fees in RM for local participant	Fees in USD for overseas participant	RM/USD payable
Conference Registration Fees			
• ***Private***	***950***	***500***	
• ***MOH***	***800***	***-***	
• ***Student***	***400***	***200***	
Early Clinical Development Symposium*	***600***	***350***	
CRC's Good Clinical Practice Workshop*	***800***	***450***	
Advanced Good Clinical Practice Workshop*	***800***	***450***	
Clinical Trial Management Workshop*	***650***	***400***	
Health & Pharmaco-economics Workshop*	***450***	***250***	
Healthcare Economics Workshop*	***600***	***350***	
Research, Publications & Citations*	***450***	***250***	
Continuing Education on Research Ethics cum Forum for Ethics Review Committees in Malaysia (FERCIM)*	***100 (Sponsored by CRC)***	***50***	
	TOTAL		

Contact

For all enquiries & return completed form to:
Ms Amy Yu
Tel : 603-40439448
Fax : 603-40439446 / 40433808
Email : nccr09@acrpm.com.my

Sponsorship & Exhibition

A limited amount of exhibition space & sponsorship opportunities are available, please contact Ms Amy Yu above

Hotel & Reservation

Enquiry on hotel reservation please contact:
Ms Dayang Jok
Tel : 604-2289246 / 2290724
Fax : 604-2261579
Email : dayang@crc.gov.my
or visit www.acrpm.com.my

Method of Payment

All payments must be submitted by 15 June, 2009 and made payable to: Associates of Clinical Research Professional Sdn Bhd

1. Either by telegraphic transfer to: PUBLIC BANK BHD
(Please fax copy of your Bank-in slip)
Address: Public Bank Berhad
Jalan Tiong Nam Branch, Level 1 & 2, Wisma Public Bank,
300, Jalan Raja Laut, 50350 KUALA LUMPUR
A/C NO: 3-1479260-17
Swift Code: PBBEMYKL

2. Or by Cheque / Bank Draft no.:
Bank Name:

Please add on 0.50 sen or 0.03% commission for outstation cheque (whichever is higher)
Send to: NCCR 09 Secretariat
ACRPM SDN BHD
2nd Floor, MMA House, 124, Jalan Pahang, 53000 Kuala Lumpur
Tel: +603-4043 9448 Fax : +603-40439446
E-mail: nccr09@acrpm.com.my
Attention: Ms Amy Yu

Cancellation

Any cancellation must be made in writing to the organizers.
- *Full refund for cancellation at least 2 weeks before date of workshop;*
- *50% refund for cancellation within 1 week;*
- *No refunds for cancellations less than 1 week or no show.*

****In the event of insufficient participation, the organizer reserves the right to cancel any of the workshops or seminars advertised above. Participants who have paid up will be refunded in full.***