Clinical Research Malaysia (1006282-X)
Address: Suite E-10-20, Amcorp Business Suites,
Menara Melawangi, Amcorp Trade Centre,
No.18, Jalan Persiaran Barat,
46050 Petaling Jaya, Selangor
Tel: 603-79605153 **Fax:** 603-79321940
Website: www.clinicalresearch.my

P1RP – Development of Phase 1 Clinical Trial Guideline

Date: 20th – 21st May 2016
Venue: Shangri-La Putrajaya
Meeting Room 2 & 3, Level 1

Workshop goals

- To produce Malaysia Guidelines on Phase 1 clinical trial registration, review and conduct.
- To review and identify criteria for conducting Phase I studies to cater to the Malaysian local ecosystem.

AGENDA
Friday, 20th May 2016

Time	Details		Venue
14:45 – 15:00	**Check-in, Registration and Refreshment**		**Dewan Putra Perdana, Level 1**
15:00 – 15:05	**Welcome Address** *by Dr. Akhmal Yusof, CEO of Clinical Research Malaysia*		**Dewan Putra Perdana, Level 1**
15:05 – 15:30	**Keynote Address: P1RP and the Malaysian Ecosystem** *by YB Datuk Seri Dr. S. Subramaniam, Minister of Health, Malaysia*		**Dewan Putra Perdana, Level 1**
15:30 – 16:00	**Coffee Break**		**Meeting Room 3**
16:00 – 16:30	**Phase I Realization Project (P1RP) – An Introduction** *by Dr. Akhmal Yusof, CEO of Clinical Research Malaysia*		
16:30 – 17:15	**An Overview of the Design of Phase I Clinical Trials** *by Mr. Ashish Jain, Vice President & Head, Early Clinical Development-Asia Pacific, Quintiles*		**Dewan Putra Perdana, Level 1**
17:15 – 17:30	**Chairperson Messages** *by Prof Datuk Dr. Looi Lai Meng*		**Dewan Putra Perdana, Level 1**
17:30 – 18:15	**GROUP DISCUSSION**		
	Group 1 Topic: Regulatory	Group 2 Topic: Protocol & Contracts	**Meeting room 2 & 3**
18:15 – 20:00	**Dinner**		**Palm Hill Cafe**
20:00 – 20:45	**GROUP DISCUSSION**		
	Group 1 Topic: Ethics	Group 2 Topic: Risk Assessment & Management	**Meeting room 2 & 3**
20:45 – 21:00	Closing notes		

Clinical Research Malaysia (1006282-X)
Address: Suite E-10-20, Amcorp Business Suites,
Menara Melawangi, Amcorp Trade Centre,
No.18, Jalan Persiaran Barat,
46050 Petaling Jaya, Selangor
Tel: 603-79605153 **Fax:** 603-79321940
Website: www.clinicalresearch.my

Saturday, 21st May 2016

Time	Details		Venue
8:30 – 9:15	**Pharmaceutical Considerations in the Preparation and Conduct of Early Phase Clinical Trials** *by Dr. Linda B Hakes, Pharmaceutical Scientist, Chairman of the Academy of Pharmaceutical Sciences, UK*		**Meeting room 2**
9:15 – 9:30	**Q&A**		
9:30 – 10:15	**GROUP DISCUSSION**		
	Group 1 Topic: Trial subjects	Group 2 Topic: Pharmacy and pathology laboratory	**Meeting room 2 & 3**
10:15 – 10:30	Coffee break		
10:30 – 11:15	**GROUP DISCUSSION**		
	Group 1 Topic: Investigational products	Group 2 Topic: Confidentiality	**Meeting room 2 & 3**
11:15 – 12:00	**GROUP DISCUSSION**		
	Group 1 Topic: Compensation	Group 2 Topic: Data management	**Meeting room 2 & 3**
12:00 – 13:00	**Lunch**		**Palm Hill Cafe**
13:00 – 13:45	**GROUP DISCUSSION**		
	Group 1 Topic: Biotechnology products & radioactive substances	Group 2 Topic: Resuscitation procedures, equipment, medicines and training	**Meeting room 2 & 3**
13:45 – 14:30	**GROUP DISCUSSION**		
	Group 1 Topic: Non-investigational medicinal products	Group 2 Topic: Essential documents	**Meeting room 2 & 3**
14:30 – 15:15	**GROUP DISCUSSION**		
	Group 1 Topic: Project management and monitoring & Quality Management	Group 2 Topic: Qualified persons	**Meeting room 2 & 3**
15:15 – 15:30	**Coffee break**		
15:30 – 16:15	**GROUP DISCUSSION**		
	Group 1 Topic: Health and safety	Group 2 Topic: Pharmacovigilance & Safety record of Phase I trials	
16:15 – 16:30	Closing notes		

Clinical Research Malaysia (1006282-X)
Address: Suite E-10-20, Amcorp Business Suites,
Menara Melawangi, Amcorp Trade Centre,
No.18, Jalan Persiaran Barat,
46050 Petaling Jaya, Selangor
Tel: 603-79605153 **Fax:** 603-79321940
Website: www.clinicalresearch.my

Participants

1. **Dato' Dr. Chang Kian Meng** (Consultant Haematologist, Ampang Hospital and Chairman of Medical Research and Ethics Committee)
2. **Prof Datuk Dr. Looi Lai Meng** (Professor of Pathology, University of Malaya)
3. **Prof Datin Dr. Zahurin bt Mohamed** (Professor at Department of Pharmacology, University of Malaya)
4. **Dr. GR Letchuman** (Consultant Endocrinologist, Hospital Raja Permaisuri Bainun)
5. **Dr. Lee Toong Chow** (Managing Director, Info Kinetics Sdn Bhd)
6. **Prof Dr. Abd Rashid Abd Rahman** (Clinical Pharmacologist, An Nur Medical Centre)
7. **Dr. Ami Fazlin Syed Mohamed** (Centre Head, Herbal Medicine Research Centre, Institute of Medical Research)
8. **Mr Nicholas Leow** (Principal Assistant Director, National Pharmaceutical Control Bureau)
9. **Mdm Yam Pei Ching** (Principal Assistant Director, National Pharmaceutical Control Bureau)