Emerged! Professional Intermediate Study Coordinator Training Workshop

Speaker	Profile	Topic in Emerged! workshop
Dr Cheong Yuet Meng **President, Society of Clinical Research Professionals Malaysia (SCRPM)** **Clinical advisor, SunMed Clinical Research Centre**	Presently she is the Associate Professor of Medical Microbiology and Clinical Investigation Unit, Jeffrey Cheah School of Medicine & Health Sciences and Clinical Advisor to SunMed Clinical Research Centre, Sunway Medical Centre. In March 2011, she was elected the President of the Society of Clinical Research Professionals, Malaysia (SCRPM) formally known as the Association of Clinical Research Professionals, Malaysia (ACRPM). Dr. Cheong started her career with the Ministry of Health, Malaysia at the Institute for Medical Research. Her main areas of research were in Clinical Microbiology & Antibiotic Resistance and she has published over 60 papers in peer review journals. She was also the Dean of the IMR Postgraduate Diploma in Medical Microbiology from 1990-94, that was held annually under the aegis of the South East Asia Ministers' of Education & Tropical Medicine Program. In 1994, she joined Pfizer, a leading Pharmaceutical R&D Company, initially as the Medical Director of Pfizer Malaysia/Singapore/Brunei and was later promoted to be the Regional Director of Clinical Operations for Asia. During her 13 years in the pharmaceutical industry she has developed and introduced a number of Clinical Trials to Asia. She is well versed in the operational, regulatory and ethical aspects of conducting clinical trials in various therapeutic areas and is actively involved in the training of investigators in Good Clinical Practice (GCP). After she retired from Pfizer, she continued her work in Clinical Research in Monash University Sunway Campus and has received 2 Pro-Vice Chancellor Awards for Excellence, one for organising the first GCP workshop in Monash and another for setting up a Clinical Research Unit at the Medical School. She is	• GCP refresher • Clinical pathway of Study Coordinator

	also instrumental in the setting up of the SunMed CRC and the Sunway Medical Centre Independent Research Ethics Committee (SREC).	
Dr Yim Poh Yin **Member, Joint Penang Independent Ethics Committee (JPEC)** **Medical monitor (contract), Gleneagles CRC (Pte) Ltd, Singapore**	Dr Yim has been involved in clinical trials at various levels since 1998. Presently, she conducst ethical review of clinical trials as a member of the Joint Penang Independent Ethics Committee, which is set up jointly by Penang Medical College and Info Kinetcs and also work in pharmacovigilance as a contract Medical Monitor for selected Phase 2 clinical trials in Gleneagles CRC (Pte) Ltd., Singapore. As early as 1998, she worked with Pfizer as a product physician and managed Phase 2 and 3 clinical trials. As a member of the pharmacovigilance team in Pfizer, she also oversaw reporting of adverse events in clinical trials. Later, she joined the Info Kinetics (a Penang-based research management organization) (2001-2007) as medical manager and research physician. As the research physician, she oversaw the clinical aspects of the Phase 2-3 clinical and bioequivalence trials as well as acted as a co-researcher in some of these trials. From this point forward up till now, she was a regular trainer in the Ministry of Health Malaysia Good Clinical Practice (GCP) certification courses. She has also been an invited speaker in Research Ethics Conferences in Singapore and Malaysia. As an active member in the clinical research industry, she has organized GCP workshops in Penang training local researcher teams. When she later joined the Penang Medical College (2007-2008), she was involv in a few diabetes drug trials as a co-researcher and Project Manager for the National Malaysian Metabolic Syndrome Epidemiology Study 2007.	• Ethical aspects of clinical trial • Revisiting informed consent
Ms Jenny Tan	Ms Jenny's present role is a clinical quality lead for Asia region with Pfizer. Her main responsibilities are to promote quality	• QC & QA aspects of Clinical Trial

	management compliance, inspection readiness, process improvements and oversight needed to ensure high quality performance of country clinical operations in Asia, and these countries include China, Hong Kong, Taiwan, India, Pakistan, Thailand, Philippines, Indonesia and Malaysia/Singapore. She started her career as a registered nurse and later became a clinical instructor in the operating theatre in Malaysia. In the year of 1997, she joined Pfizer as a regional Clinical Research Associate for region Malaysia/Singapore. From Dec 1997 to Jan 2005, she managed trials in various therapeutic areas from pre-trial assessment to study close-out including regulatory submission and budgeting. Throughout these 7 years, she has acquired different position and has engaged into managing AE/SAEs reporting Pfizer's safety system and regulatory authority and also has had some regulatory experience in managing product renewal between years 2001-2002 in Malaysia. With her substantial experiences in the clinical research industry, she was promoted to be the Quality Standards & Process Implementation Manager for Malaysia/Singapore in the year 2005. At that time, she was responsible to drive quality & process improvements in the country office through audit &inspection readiness activities and support and also provide training on SOP/process, new hires and conduct CRAs workshops. One of the key achievements of Ms Jenny was that she has received Pfizer's Charlie award in year 2007 for her contribution to the CRA certification program.	
Mr Muraliydharann **Regional Operations Director (Asia Pacific)** **PDP couriers**	Mr Muraliy has had more than 15 years of working experience in the life science logistics industry. He has been working for established Multi National Companies, namely World Courier, Marken and is currently working with PDP Couriers. With his exposure and experience in the	• Laboratory and Bio-samples packing & shipment

	logistics industry, he has in-depth knowledge in managing, operations and provides cold chain solutions and he was instrumental in developing cold chain infrastructural and network capabilities across Asia Pacific Region for the companies that he has been working with. He is a specialist in handling all types of dangerous goods shipments and he also provides training in operations, cold chain shipments handling, handling in clinical trials. Mr Muraliy has spear headed in operational set up in Asia Pacific Region for current and previous employment. He had vast experience in advising in the provision of packaging with respect to samples shipping and also having full knowledge and experience in handling and shipping Pharmaceutical products in Envirotainer, Enviro-Cooler, etc;. With his expertise and substantial past experiences, he make an expert advisor in operations, logistics and Government regulatory requirements for various countries across Asia Pacific Region in clinical trials, samples shipping.	
Ms Anna Lee **Clinical Study Manager** **Info Kinetics Sdn Bhd**	Ms Anna joined Info Kinetics as a study coordinator in the year of 2007 and later promoted to clinical study manager in the year of 2010. She has managed and coordinated more than 20 clinical trials in the past and still counting. During her role as a study coordinator, she has acquired substantial experiences in coordinating site operations and clinical protocol execution. She has developed and implemented various standard operating procedures with various participating sites for smooth clinical research operations and ensures site GCP compliance. She also involved in clinical trial agreement and site budget review. With her experience in the clinical research industry, she also conducts protocol review and site feasibility review and provides expertise advice in	• Investigator product/study drug management • Source documentation/ CRF • Record keeping & retention • Archival process • Safety assessment, AE/ConMed documentation

	clinical study management. With her substantial exposure in this industry, she has helped in setting up clinical trial site that meets industry and regulatory standards. Presently, she is overseeing all clinical operations that are being conducted at 5 institutions in Penang. She had developed study coordinator manual internally for in-house training and has been speaker for Emerged! Professional Intermediate Study Coordinator Training workshop last year and BeST program (jointly organized by PSDC Penang and Biotechcorp)	
Ms Patricia Khoo **Senior Study Coordinator** **Info Kinetics Sdn Bhd**	Ms Patricia graduated with a major in drug design and development from the university of Queensland. She joint Info Kinetics as a study coordinator in the year of 2009. She is currently coordinating more than 6 studies at 4 institutions. She has in-depth experiences in all aspects of the roles and responsibilities of study coordinator and sponsor audit. Presently, she is also conducting pre-study assessment and be the liaison between sponsor/CRO and all hospitals in Penang for feasibility study. She is also heading the recruitment team for patient recruitment and education program. She is also a PSMB certified trainer in designing and delivering competency-based training program. She also has experience in providing study coordinator training internally and externally. She has been speaker and facilitator for Emerged! Professional Intermediate Study Coordinator training workshop 2010.	• Drug Design & Development • Know our industry player • Planning & Execution of protocol • PSV/SIV • Tips to be a good SC