

CLINICAL TRIAL MAGNIFIER

Conference TOPICS

- The Importance of Clinical Pharmacology in Clinical Trials
- The Impact of the EU Clinical Trial Directive 2001/20/EC
- Possible Clinical Research Professionals Career Pathways
- Established and Emerging Trial Networks
- Essence of Project Management Skills
- The Role of Asia in Global Drug Development
- Current Trends in Regulation
- US FDA Inspections in Established versus Emerging Regions
- Risk Management of First-in-man Trials
- Accreditation of Human Protection Programs
- Why Clinical Trials in Eastern Europe?
- Negotiating Clinical Trial Budgets
- Institutional Indirect and Administrative Fee
- Negotiating Clinical Trial Agreements
- Clinical Research Centre Infrastructure Development
- Investigator Breast Cancer Trial Network in China and Asia
- Educating Study Site Staff on GCP Compliance
- Educating IRB Members

and more

Next Issue

November 2009, Volume 2, Issue 11
Clinical Trial Magnifier
November 2009
Conference Coverage

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- 584-589 *Magnifier* Advisory Board Members; 103 in number.
- 590-592 The most recent - October 2009 - industry sponsored clinical trials registered.

Pages Clinical Trial Conference

- 508-583 Clinical Trial Magnifier November 2009:
- Conference Program
 - Conference Speakers' Profiles
 - Conference Abstracts
 - Conference Sponsors
 - Conference Supporting Organizations

Clinical Trial Magnifier
2009 Conference - Hong Kong
November 13-15, 2009 (Friday - Sunday)
LI Ka Shing Faculty of Medicine Building, 21 Sassoon Road, The University of Hong Kong

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Clinical Research Professionals

Discovering and developing new medicinal products is an extremely complex process. It can take decades and involve professionals in virtually all working areas – from business, law, management and media to engineering, basic sciences, laboratory sciences, pharmacology and medicine. A discovery made in a single research laboratory extends to sophisticated, specialist pre-clinical testing research laboratories before entering large-scale clinical trials involving thousands of patients, conducted by hundreds of clinical investigators in dozens of countries.

The drug development process is essentially a tremendous, multi-team marathon relay race, as one group of professionals hands over responsibility to the next.

More and More Subscribers

The *Clinical Trial Magnifier* was launched in January 2008 and to date 12,293 clinical research professionals have signed up as subscribers.

During the past two months alone we have had the privilege of welcoming 823 clinical research professionals as new subscribers; about half from North America, 20% from Europe and 15% from Asia. About half are clinical professionals, 65% have MD/PhD/Master degrees, 40% are from universities and 27% are life-science industry employees. This new subscriber profile very much represents the profile of all *Magnifier* subscribers; a mixture of professionals from both academia and the industry, and also some significant representatives from governmental bodies and media. The *Magnifier* subscriber community is thus growing by the month and today integrates professionals from 144 countries.

We are receiving quite a few positive messages from our subscribers – reflections and/or queries. Now, we wish to have more input from our readers – from you. How can we take the *Magnifier* to the next step? What is lacking? How can communication between subscribers be enhanced? What topics are of highest interest? What about trial opportunity listings? What about readers input?

Please, respond to
editorialboard@clinicaltrialmagnifier.com

First *Magnifier* Conference

November 13–15, 2009 in Hong Kong

By the end of 2008, we realised that the *Magnifier* had become a multidisciplinary forum for clinical research professionals worldwide, specifically addressing issues surrounding the globalisation process of clinical research. So it was not difficult to identify the obvious need for an international conference addressing major current issues and trends of interest and relevance to both clinical trial sponsors and investigative sites – with topics ranging from Agreements and Budgets to Operations and Regulations. Most of those issues are global in nature and some can be standardised. The focus of the *Clinical Trial Magnifier* Conference is to be a forum for Globalization and Standardisation.

The first *Clinical Trial Magnifier Conference* will be held in Hong Kong on November 13–15, 2009. It will address the most pressing current issues, including:

- What contract terms are critical in a clinical trial agreement?
- What site duties can be delegated?
- What items can be charged for in a trial budget?
- What are the necessary qualities to become a wonderful investigator?
- What are the incentives for an investigator to participate in a sponsored clinical trial?

The *Magnifier Conference* will focus on streamlining sponsor–investigator interaction, by addressing the most central, key aspects. It will address the latest legal, regulatory, financial, contractual, operational, ethical and quality assurance aspects of clinical trials – and most specifically, the interaction between sponsors and investigators, and trial conduct.

As such, the *Magnifier Conference* will be of critical interest to both clinical research novices or veterans....indeed, any professionals working anywhere in the world with study sponsors, research sites, or CROs.

This *Magnifier* issue provides details of the upcoming *Magnifier Conference* – programme, speakers with their abstracts, chairpersons, sponsors, collaborators and partners. The best you can get!

Welcome to Hong Kong in November 2009 – when the weather will be perfect!

Johan Karlberg

Editor, *Clinical Trial Magnifier*

Hong Kong, October 2009

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- Clinical study report

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Global clinical study

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Contract manufacturing

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Contract MR etc.

Friday - November 13, 2009

12:00 - 13:00	Registration		
13:00 - 13:15	Chairman's Welcome and Housekeeping Remarks		
	Johan P.E. KARLBERG, MD, PhD, BSc, Director, Clinical Trials Centre, The University of Hong Kong, Hong Kong, China		
13:15 - 14:35	MAGNIFIER's Workshop I: Legal Requirements, Research Ethics and Informed Consent – The Basics		MAGNIFIER's Workshop II: Clinical Trial Players and Responsibilities – The Basics
Chair:	Marjorie A. SPEERS, PhD, President and CEO, Association for the Accreditation of Human Research Protection Programs, Inc., Washington, United States		Melvin K.M. TOH, MD, MSc, Vice President, Pharmaceutical Development, CK life Sciences International Inc., Hong Kong, China
Chair:	Suzanne GAGNON, MD, FACP, Chief Medical Officer, ICON Clinical Research, North Wales, Pennsylvania, United States		Peter OBEROSLER, PhD, Chief Operating Officer, Harrison Clinical Research Deutschland GmbH, Munich, Germany
13:15 - 13:35	New Approaches in the Development of Medicines for Children		Clinical Trial Players and Responsibilities
	Dora MATHIASZ, MD, MBA, Medical Director, GlaxoSmithKline, Budapest, Hungary		K.C. LAU, PhD, Director of Clinical Operations, PPD, Hong Kong, China
13:35 - 13:55	Vulnerable Clinical Trial Subjects		Communicating with Regulatory Authority
	Dinesh Kumar BADIYAL, MBBS, MD (Pharmacology) , Diploma in Clinical Research, Professor and Head, Department of Pharmacology, Christian Medical College and Hospital, Ludhiana, India		Chaya MAZOUZ, BSc, RN, MA, VP Clinical and Regulatory Affairs, Pluristem Therapeutics Inc., Haifa, Israel
13:55 - 14:15	Elements of Informed Consent Forms		The Perfect Sponsor
	Selene TAM, PhD, MMedSc, BHSc, RN, Project Operation Manager, Clinical Trials Centre, The University of Hong Kong, Hong Kong, China		Kyung-Soo KIM, MD, PhD, Director, Clinical Trial Center & Clinical Research Coordinating Center, Catholic University of Korea, Seoul, South Korea
14:15 - 14:35	Efficient Adverse Event Reporting		The Wonderful Investigator
	James FAN, MD, MBS, Associate Director, Medical Affairs and Drug Safety/ Asia Pacific, ICON Clinical Research Pte Ltd., Singapore		Vikram GOTA, MBBS, MD, Assistant Professor, Clinical Pharmacology, ACTREC, Tata Memorial Centre, Mumbai, India
14:40 - 15:10	Coffee Break - Networking		
15:10 - 15:55	Satellite Symposium I	Satellite Symposium II	Satellite Symposium III
Chair:	Yuji KUMAGAI, MD, PhD, Director, Clinical Trial Center, Kitasato University East Hospital, Tokyo, Japan	Edmund S. TSUEI, BSc, MSc, PhD, Regional Head, Asia-Pacific-Africa , Pharma Development Operations, Roche Products Pty Limited, Sydney, Australia	Rodney GALE, BSc, DPhil, MBA, Principal Consultant, Rodney Gale Associates, London, United Kingdom
	The Importance of Clinical Pharmacology in Clinical Trials	The Impact of the EU Clinical Trial Directive 2001/20/EC	Possible Clinical Research Professionals Career Pathways
	Ruiwen ZHANG, MD, PhD, DABT, Clinical Pharmacology, Pharmacology and Toxicology Director, Cancer Pharmacology Laboratory, University of Alabama, Birmingham, United States	Markus HARTMANN, PhD, MDRA, European Consulting & Contracting in Oncology, Trier, Germany	Ling SU, PhD, Vice President, Clinical Research & Development Asia Pacific, Wyeth Pharmaceutical Co., Ltd., Shanghai, China
			Possible Clinical Research Professionals Career Pathways (in the CRO Industry)
			Philip AU, MMedSc, MBA, RNAssociate Portfolio Director, Project Management Group, PAREXEL International, (Hong Kong), Hong Kong, China
16:00 - 18:00	MAGNIFIER's Workshop III: Study Site Management – Established and Emerging Trial Networks		MAGNIFIER's Workshop IV: Project Management and Monitoring – The Basics
Chair:	Rodney GALE, BSc, DPhil, MBA, Principal Consultant, Rodney Gale Associates, London, United Kingdom		Frank FAN, MD, MBA, Medical Director, Medical Department, Wyeth Pharmaceutical Co., Ltd., Hong Kong, China
Chair:	Jerome B. ZELDIS, MD, PhD, CEO, Celgene Global Health / Chief Medical Officer, Celgene Corporation, New Jersey, United States		Jing-Ping YEO, PhD, Associate Director, Project Management, Quintiles East Asia Pte Ltd., Singapore
16:00 - 16:20	Clinical Research Collaboration Network (CRCN) in Thailand		Essence of Project Management Skills
	Pyatat TATSANAVIVAT, MD, Director, Clinical Research Collaboration Network (CRCN), Bangkok, Thailand		Soo-Yeon PARK, BSc, Senior Clinical Research Manager, GSK Korea, Seoul, South Korea
16:20 - 16:40	Utilization of Trial Networks		Selecting Responsible Monitors
	Peter OBEROSLER, PhD, Chief Operating Officer, Harrison Clinical Research Deutschland GmbH, Munich, Germany		Emily TAN, MSc, Director, Clinical Research Asia, PharmaNet Pte Ltd., Singapore
16:40 - 17:00	Korea National Enterprise for Clinical Trials (KoNECT)		Key Monitoring Roles and Responsibilities
	Dongho LEE, MD, MBA, Department of Anesthesiology and Clinical Pharmacology Executive Director of Clinical Research Center, Asan Medical Center, South Korea		Peng CHAN, BSc (Hons), Director, Research2Trials Clinical Solutions, Singapore
17:00 - 17:20	Clinical Research Centre (CRC) in Malaysia		Proficiency in Writing Monitor Reports and Follow-up Letters
	Teck-Onn LIM, MD, Director, Clinical Research Centre, Ministry of Health, Kuala Lumpur, Malaysia		Daniel LI, BSc (Hon), Senior Manager, PAREXEL International (Hong Kong) Co. Ltd., Hong Kong, China
17:20 - 17:40	Optimizing Partnerships between Public and Private Organizations in Driving Clinical Research		Important Aspects of Site Interaction by Sponsor/CRO
	Shyard WONG, MBBS, Director, Clinical Research Unit, South East Asia, Sanofi-aventis Singapore Pte Ltd., Singapore		Yuji KUMAGAI, MD, PhD, Director, Clinical Trial Center, Kitasato University East Hospital, Tokyo, Japan
17:40 - 18:00	Discussion		Discussion
17:40 - 18:00	Cultural Reception - Networking		

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Saturday - November 14, 2009

08:00 - 09:00	Registration
09:00 - 11:00	Regulations – Hot Topics
Chair:	Vikram GOTA, MBBS, MD, Assistant Professor, Clinical Pharmacology, ACTREC, Tata Memorial Centre, Mumbai, India
Chair:	Pyatat TATSANAVIVAT, MD, Director, Clinical Research Collaboration Network (CRCN), Bangkok, Thailand
09:00 - 10:00	Plenary Lecture: Current Trends in Regulation
	Henry MILLER, MD, PhD, Research Fellow, The Hoover Institution, Stanford University, Stanford, United States
10:00 - 10:30	US FDA Inspections in Established versus Emerging Regions
	Suzanne GAGNON, MD, FACP, Chief Medical Officer, ICON Clinical Research, North Wales, Pennsylvania, United States
10:30 - 11:00	Risk Management of First-into-man Trials
	Ulf MALMQVIST, MD, PhD, Head of Operation, Clinical Research and Trial Centre, Lund University Hospital, Lund, Sweden
11:00 - 11:30	Coffee Break – Networking
11:30 - 13:00	Research Ethics – Principal Population
Chair:	Simon DONELL, BSc, FRCS (Orth), MD, Honorary Professor & Consultant Orthopaedic Surgeon, Norfolk and Norwich University Hospital, Norwich, United Kingdom
Chair:	Markus HARTMANN, PhD, MDRA, European Consulting & Contracting in Oncology, Trier, Germany
11:30 - 12:00	Accreditation of Human Protection Programs
	Marjorie A. SPEERS, PhD, President and CEO, Association for the Accreditation of Human Research Protection Programs, Inc., Washington, United States
12:00 - 12:30	Ethical Problems with Clinical Trials in Russia
	Boleslav L. LICHTERMAN, MD, PhD, Senior Researcher, Russian Academy of Medical Sciences, Moscow, Russia
12:30 - 13:00	Research Ethics and Informed Consent
	Melody H. LIN, PhD, Deputy Director & Director of International Activities, Office for Human Research Protections, Department of Health and Human Services, Rockville, United States
13:00 - 14:00	Lunch – Networking
14:00 - 16:00	Operation – Globalization
Chair:	Kyung-Soo KIM, MD, PhD, Director, Clinical Trial Center & Clinical Research Coordinating Center, Catholic University of Korea, Seoul, South Korea
Chair:	Ole M. BECH, MD, PhD, Vice President, Novo Nordisk (China) Pharmaceuticals Co., Ltd., Beijing, China
14:00 - 15:00	Plenary Lecture: The Role of Asia in Global Drug Development
	Edmund S. TSUEI, BSc, MSc, PhD, Regional Head, Asia-Pacific-Africa, Pharma Development Operations, Roche Products Pty Limited, Sydney, Australia
15:00 - 15:30	Why Clinical Trials in Eastern Europe?
	Andrei KRAVCHENKO, MD, PhD, Managing Director, Representative Office in Ukraine, Harrison Clinical Research Deutschland GmbH, Kiev, Ukraine
15:30 - 16:00	How Does a Bio-Pharma go Global?
	Jerome B. ZELDIS, MD, PhD, CEO, Celgene Global Health / Chief Medical Officer, Celgene Corporation, New Jersey, United States
16:00 - 16:30	Coffee Break – Networking
16:30 - 18:00	Magnifier Census Polling
Chair:	Johan P.E. KARLBERG, MD, PhD, BSc, Director, Clinical Trials Centre, The University of Hong Kong, Hong Kong, China
Chair:	Tzy-Jyun YAO, PhD, MSc, BSc, Associate Professor, Clinical Trials Centre, The University of Hong Kong, Hong Kong, China
	Study Site Location Selection Criteria
	Investigator-Initiated Clinical Studies
	Phase I Trial Safety Concerns
	Institutional Indirect Fees and Administrative Fees for Industry Sponsored Clinical Trials
	Incentives for Participation in Industry Sponsored Clinical Trials
	Clinical Research Guidelines
	Summary
16:00 - 17:30	MAGNIFIER's GCP & Research Administration Professional Exam (GRAPE)
19:30	Participants' Dinner – sign up/reserved tables/set menu/popular restaurants (no host)
19:30	Speakers' Dinner – by invitation

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Sunday - November 15, 2009

08:00 - 09:00	Registration
09:00 - 11:00	Budgets – Realistic
Chair:	Alan PAAU, CLP, MBA, PhD, Executive Director & Vice Provost, Technology Transfer & Economic Development, Cornell University, Ithaca, New York, United States
Chair:	Teck-Onn LIM, MD, Director, Clinical Research Centre, Ministry of Health, Kuala Lumpur, Malaysia
09:00 - 09:30	Introduction to Clinical Trial Budgets
	Ole M. BECH, MD, PhD, Vice President, Novo Nordisk (China) Pharmaceuticals Co., Ltd., Beijing, China
09:30 - 10:00	Study Site Budget Development
	Henry YAU, MBA, BSc, Assistant Director & Chief Business Officer, Clinical Trials Centre, The University of Hong Kong, Hong Kong, China
10:00 - 10:30	Negotiating Clinical Trial Budgets
	Frank FAN, MD, MBA, Medical Director, Medical Department, Wyeth Pharmaceutical Co., Ltd., Hong Kong, China
10:30 - 11:00	Institutional Indirect and Administrative Fee
	Tatyana BENISHEVA, MD, PhD, Associate Professor, Drug Regulatory Affairs, Faculty of Public Health, Medical University, Sofia, Bulgaria
11:00 - 11:30	Coffee Break
11:30 - 13:00	Agreements – Outline
Chair:	Chaya MAZOUZ, BSc, RN, MA, VP Clinical and Regulatory Affairs, Pluristem Therapeutics Inc., Haifa, Israel
Chair:	Henry YAU, MBA, BSc, Assistant Director & Chief Business Officer, Clinical Trials Centre, The University of Hong Kong, Hong Kong, China
11:30 - 12:00	Development of Clinical Trial Agreements
	Audrey SHUM, LLB (HKU), LLM (Cantab), Consultant of Clifford Chance, Hong Kong, China
12:00 - 12:30	Negotiating Clinical Trial Agreements
	Rodney GALE, BSc, DPhil, MBA, Principal Consultant, Rodney Gale Associates, London, United Kingdom
12:30 - 13:00	Principles of Investigator Initiated Trial Agreements
	Alan PAAU, CLP, MBA, PhD, Executive Director & Vice Provost, Technology Transfer & Economic Development, Cornell University, Ithaca, New York, United States
13:00 - 14:00	Lunch
14:00 - 16:00	Operation – Efficiency
Chair:	Yil-Seob LEE, MD, PhD, Director, Medical & Regulatory, GSK Korea, Seoul, South Korea
Chair:	Tatyana BENISHEVA, MD, PhD, Associate Professor, Drug Regulatory Affairs, Faculty of Public Health, Medical University, Sofia, Bulgaria
14:00 - 14:30	Clinical Research Centre Infrastructure Development
	Yuet-Meng CHEONG, MBBS, MSc, FRCPath, Associate Professor of Medical Microbiology and Clinical Investigation Unit, Monash University Sunway Campus, Selangor, Malaysia
14:30 - 15:00	Site Management Efficiency
	Jade LIU, MSc, Chief Operation Officer, Taiwan Total Management Consulting Ltd., Taipei, Taiwan
15:00 - 15:30	Clinical Research in the UK: The Comprehensive Research Networks
	Simon DONELL, BSc, FRCS(Orth), MD, Honorary Professor & Consultant Orthopaedic Surgeon, Norfolk and Norwich University Hospital, Norwich, United Kingdom
15:30 - 16:00	Investigator Breast Cancer Trial Network in China and Asia
	Louis CHOW, MBBS, MS, Honorary Clinical Professor, Clinical Trials Centre, The University of Hong Kong, Hong Kong, China
16:00 - 16:30	Coffee Break
16:30 - 18:00	Operation – Education
Chair:	Melody H. LIN, PhD, Deputy Director & Director of International Activities, Office for Human Research Protections, Department of Health and Human Services, Rockville, United States
Chair:	Ling SU, PhD, Vice President, Clinical Research & Development Asia Pacific, Wyeth Pharmaceutical Co., Ltd., Shanghai, China
16:30 - 17:00	Educating Study Site Staff on GCP Compliance
	Marisa PETERSEN, PhD, Chief Executive Officer, ARCS Australia Ltd., Sydney, Australia
17:00 - 17:30	Educating IRB Members
	Johan P.E. KARLBERG, MD, PhD, BSc, Director, Clinical Trials Centre, The University of Hong Kong, Hong Kong, China
17:30 - 17:45	Conference Summary and Closing
	Edmund S. TSUEI, BSc, MSc, PhD, Regional Head, Asia-Pacific-Africa, Pharma Development Operations, Roche Products Pty Limited, Sydney, Australia
17:45	Announcement of Next Magnifier Conference
	Johan P.E. KARLBERG, MD, PhD, BSc, Director, Clinical Trials Centre, The University of Hong Kong, Hong Kong, China
16:00 - 17:30	MAGNIFIER's GCP & Research Administration Professional Exam (GRAPE)

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CLINICAL TRIAL MAGNIFIER CHAIR

SESSION: LEGAL REQUIREMENTS, RESEARCH ETHICS AND INFORMED CONSENT – THE BASICS

Chairpersons: Nov 13, 13:15 – 14:35

Marjorie A SPEERS, PhD

Suzanne GAGNON, MD, FACP

MARJORIE A SPEERS, PhD
Washington–United States



SUZANNE GAGNON, MD, FACP
Pennsylvania–United States



Dr. Speers is the President and CEO of the Association for the Accreditation of Human Research Protection Programs (AAHRPP), which offers accreditation services globally.

Previously, she served at the National Bioethics Advisory Commission from 1999–2001, both as project director for a report on the research oversight system and as Acting Executive Director. Dr. Speers was Deputy Associate Director for Science at the Centers for Disease Control and Prevention (CDC) from 1995–2000. As the Deputy Associate Director for Science, Dr. Speers oversaw the human subjects protection program both for domestic and international research.

While at CDC, Dr. Speers held a variety of positions from 1988–1995: Director of the Division of Chronic Disease Control and Community Intervention, Chief of the Aging and Statistics Branch, and staff epidemiologist. Prior to joining CDC, she was a faculty member at the University of Texas Medical Branch and the University of Connecticut –Stamford.

Her research is focused in public health, primarily on prevention and health promotion. Dr. Speers received doctoral degrees in psychology and epidemiology from Yale University and bachelor's degree in psychology from Dickinson College.

Dr. Suzanne Gagnon – Chief Medical Officer & Executive Vice President, ICON Clinical Research

Dr. Suzanne Gagnon joined ICON in 2001 as Sr. Vice President of US Medical Affairs, Regulatory Affairs and Scientific Writing. In April of 2006, she was promoted to Global Head of Medical Affairs and Drug Safety, and in June 2008 she was named Chief Medical Officer.

Prior to joining ICON, she held various senior management positions in Medical Affairs and Clinical Research and Development at Rhone-Poulenc Rorer, Luitpold Pharmaceuticals and Omnicare Clinical Research. Her background includes eight years in academic medicine at Boston University, the University of Miami and as the Director of Clinical Research at the University of Kansas School of Medicine.

Suzanne received her medical degree from Boston University School of Medicine, is Board Certified in Internal Medicine and is a Fellow of the American College of Physicians. She has held a number of academic faculty appointments and has published articles and abstracts on drug safety and in therapeutic areas including HIV disease, chronic renal failure and oncology. She currently lectures in Pharmaceutical Product Development and Drug Safety at West Chester University.

CLINICAL TRIAL MAGNIFIER SPEAKER

Dora MATHIASZ, MD, MBA

Budapest-Hungary

Nov 13, 13:15 – 13:35

New Approaches in the Development of Medicines for Children

ABSTRACT

There is an increase of the research activity in the pediatric drug development after the recent US and European legislative changes.

There are important challenges for the drug industry in this field albeit the incentives to support the research. Ethical concerns, logistical and technical issues, economic barriers are these challenges with which the industry must face during the new drug development process.

Public-private partnership is a way for the new medicine development for children. I would like to give a good example where this partnership was successful in the vaccine development.



BIBLIOGRAPHY

After finishing her medical studies in Hungary, Dr. Mathiasz then went on to pursue her medical qualifications in Belgium, after which she began working as a clinician in Budapest and Brussels as a specialist of internal medicine.

After several years of hospital practice, she joined Wellcome, the pharmaceutical company where she is still presently working. Over the past 17 years the company went through several mergers and acquisitions to become the GlaxoSmithKline of today. Carrying the title of Medical Director, she has been leading the Medical Department of GlaxoSmithKline Hungary with several CEE regional responsibilities.

Dr. Mathiasz specializes in internal medicine and clinical pharmacology. She also has an MBA from Oxford Brookes University.

CLINICAL TRIAL MAGNIFIER SPEAKER

Dinesh Kumar BADYAL, MBBS, MD

Ludhiana-India

Nov 13, 13:35 – 13:55

Vulnerable Clinical Trial Subjects

ABSTRACT

India is going to become a hub for clinical trials. By the year 2010, 20% of all global clinical trials will take place in India. India has “Western” disease distribution, high patient numbers available, many tertiary care and specialty hospitals, large number of medical specialists, patients are generally “therapy naïve”, low cost (30–50%) advantage, no language barriers and IT-based advantages. However, over 800 million of the Indian population still survives on Rs 20.0 (US\$0.5) a day and rural poverty is on the rise. The link between poverty and health is well established where the underprivileged are more vulnerable to major health risks, as well as susceptible to being recruited in clinical trials. Since the regulatory authorities are only beginning to pull their act together and subjects are still lured to these trials, there is a pressing issue of vulnerability of these subjects of unnecessary experimentation. It has been seen that Indian regulatory agencies are weak and medical councils refuse to act against errant doctors. The Schedule Y in India takes care of the vulnerability of the subjects. It is going to be revised very soon. The majority of vulnerable patients take a number of unquantified risks—unknown short and long-term effects of the drugs; unmet treatment needs; social and economic consequences such as loss of income; loss of existing insurance cover, incidental costs such as travel, cost of seeking legal and medical advice, disturbance of domestic life and potential stigma and discrimination. The patients are not well informed about consent forms and the process. Sometimes even they are not aware that they are being enrolled into clinical trials. The ethics committee members are not well trained to handle all documentation. However, there are some centres which are following all these norms and conducting multinational clinical trials. In the present scenario, India plans to change laws to give the government power to crack down on firms carrying out unethical drug trials as it seeks to become a global hub for clinical testing, so that patient are not exposed to the risks of newer drugs and devices.



BIBLIOGRAPHY

Dr. Badyal is Professor and Head, Department of Pharmacology at Christian Medical College and Hospital in Ludhiana, India. He is trained in clinical pharmacology and research methods. His areas of interest include clinical trials, ethics in clinical research, supervising research projects and medical education. He is the editor of “The Clinical Researcher”, an official journal of Clinical Research Board. He is a member of the Institute Ethics Committee and Betty Cowan Innovation & Research Centre at his institute. Dr. Badyal is involved in conducting a number of clinical trials as principal investigator and co-investigator and serves as advisory to clinical subjects when they plan to start clinical trials. He is conducting a three-day “Clinical Research Workshop” at his institute which is co-sponsored by ICMR (Indian Council of medical Research). He has just conducted a short program for interns – “Basics of Clinical Research”, to sensitize budding doctors to the ever expanding field of clinical trials. He has published 25 papers in reputed national and international journals. He also authored two books. Dr. Badyal has presented his research papers at various national and three international conferences including IUPHAR conferences. He is currently pursuing a fellowship in Medical Education at FAIMER, Philadelphia.

CLINICAL TRIAL MAGNIFIER SPEAKER

Selene TAM, PhD, MMedSc, BHSc, RN

Hong Kong-China

Nov 13, 13:55 – 14:15

Elements of Informed Consent Forms

ABSTRACT

Informed consent is a process conducted by the investigator to the trial subject for providing information concerning the trial that are relevant to the subject's decision in participation in a clinical trial. The information is documented on an Informed Consent Form (ICF). The ICH GCP E6 guidelines state 20 elements to be included in an ICF for informed consent explanation and discussion with trial subjects. The guidelines require explanation to subjects the purpose of the trial, the trial involves research and areas that are experimental, and trial treatment and the random assignment. The subjects should be informed about the foreseeable risks and expected benefits in participating in the trial, and the alternative treatment(s) that may be available. The investigator should explain the trial procedures to be followed and the subject's responsibilities in the trial. The anticipated payment and anticipated expenses to the subjects, and compensation/treatment available in the event of trial-related injury are to be explained as well. It is required to inform the subjects that their participation is voluntary and that the subject may refuse to participate at any time. It is also required to inform the subjects that the monitor, auditor, IRB/IEC and the regulatory authority will be granted direct access to their original medical records for data verification and quality checks. The subjects should be made aware of the duration of the trial, the number of subjects involved, the foreseeable circumstances that the trial may be terminated, and the person(s) to contact for further information. How confidential information will be handled should also be explained to the subjects. The subjects should also be told that they will be informed in a timely manner on any new information that may be relevant to their willingness to continue participation in the trial.



BIBLIOGRAPHY

Dr. Selene Tam is the Assistant Director and Project Operation Manager of the Clinical Trials Centre (CTC), Li Ka Shing Faculty of Medicine, The University of Hong Kong (HKU). She had her first degree in Nursing and PhD degree in paediatric medicine, HKU, in 1999. She obtained her master degree in Medical Science specializing in Clinical Trials Research Methodology.

Dr. Tam has experience in working as study site personnel and as sponsor's designate. She joined CTC in 1998, working as Site Manager to compile trial applications and subsequent communications of about 80 clinical trials to the local Institutional Review Board. She worked as a Study Site and Recruitment Manager in a global phase III vaccine trial in Hong Kong and led a study team to recruit 360 healthy subjects within 3 weeks.

Since 2003, Dr. Tam has been working as a Project Operation Manager providing one-stop comprehensive CRO services to Sponsors; protocol development, study feasibility study, pre-study planning, setting up study, monitoring, data management and statistics. Up to date, she has been involved in developing 13 clinical trial protocols and has managed 25 clinical trials.

Dr. Tam has taught in Clinical Trial Research Methodology in Master of Public Health and Master of Medical Science program in HKU since 2000. She conducted several investigator training workshops sponsored by international pharma. She was also involved in training on GCP to Ethics Committee members in Hong Kong and staff in Pharmaceutical Registration Section in Department of Health, Hong Kong.

CLINICAL TRIAL MAGNIFIER SPEAKER

James FAN, MD, MBS

Singapore

Nov 13, 14:15 – 14:35

Efficient Adverse Event Reporting

ABSTRACT

Drug safety is the process of identifying, evaluating and responding to Adverse Drug Reactions (ADRs) in clinical trials and safety issues concerning medicinal products and during postmarketing surveillance. This presentation will review the legislation and guidelines that govern the drug safety during the clinical trial in the world, and will focus on drug safety management in global trials. It will also explain the procedures on how to perform SUSAR reporting, review specific safety-related topics, the unblinding process, and review the process which involves Institutional Review Boards (IRB), regulatory and investigator reporting and case processing for safety data base. The current status of drug safety reporting in Asia-Pacific countries will be reviewed. ICON experiences in drug safety management will be shared. This presentation will end with a discussion about the future of safety reporting requirements such as electronic submission and harmonization in Asia.



BIBLIOGRAPHY

Dr. James Fan is Associate Medical Director in ICON Clinical Research Ltd (CRO) in charge of medical and safety affairs in Asia-Pacific rim. James Fan joined ICON in August 2006, having previously held the position of Medical Director in Taiwan-based CRO, Protech Pharmservices Corporation, and American Biotech, Optimer Pharmaceuticals, Inc for 7 years. As a certified physician of Internal Medicine, he was trained in the Shanghai Medical University Hospital, he has over 11 years of clinical practice experience, then he received diagnostic medical imaging training in Greenlane Hospital, Auckland University School of Medicine, New Zealand. He was also awarded Master of Business Study by Massey University, New Zealand.

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CLINICAL TRIAL MAGNIFIER CHAIR

SESSION: CLINICAL TRIAL PLAYERS AND RESPONSIBILITIES – THE BASICS

Chairpersons: Nov 13, 13:15 – 14:35

Melvin KM TOH, MD, MSc

Peter OBEROSLER, PhD

Melvin KM TOH, MD, MSc
Hong Kong–China



Peter OBEROSLER, PhD
Munich–Germany



Dr. Melvin Toh is Vice President, Pharmaceutical Development at CK Life Sciences Int'l Inc, with oversight of preclinical development, clinical development, regulatory affairs and clinical quality assurance. CK Life Sciences' pharmaceutical operations include the in-house CK Cancer Research Institute in Hong Kong and associate/subsidiary companies in North America – Wex Pharmaceuticals Inc (Canada) and Polynoma LLC (US).

Dr. Toh is also actively involved in pharmaceutical business development activities, including identification of partnering opportunities, participation in due diligence, partner negotiations and relationship management.

Dr. Toh holds a medical degree from the National University of Singapore and an MSc degree from the University of London, and has almost 20 years of experience in clinical medicine and pharmaceutical R&D.

He has held management and scientific leadership positions in Asia and the US. Prior to joining CK Life Sciences in 2008, he was Director in Oncology Development, Pfizer Global R&D, based in the US, where he headed a team of scientists working on the clinical development of new cancer drugs. He was previously the Head and Medical Director of the Pfizer Clinical Research Unit at Singapore General Hospital, Pfizer's only early phase clinical research unit in Asia.

Dr. Oberosler graduated with a degree in molecular biology in 1993. After receiving his PhD from the University of Munich at the Max-Planck-Institute in 1996, he started his career in clinical research at Bristol-Myers Squibb as a CRA. After gaining in-depth insight into clinical trials, he moved on to a management position at PPD where he worked as a line manager and later country manager in a number of countries for 8 years.

Since a year and a half ago, he assumed responsibility as COO at Harrison Clinical Research, heading Clinical Operations, Biostatistics, Medical Writing and a Phase I/IIa clinic in Germany and CEE.

Over the years Dr. Oberosler gained extensive experience in clinical research from different perspectives through supervising and managing department and country managers, strategically developing areas of his responsibility (e.g. clinical research in Poland, Czech and Slovak Republics, Ukraine, Russia and Germany), and working on business development.

He is particularly interested in increasing clinical research in the CEE region but also interested in making Phase I/IIa studies more attractive in Germany.

CLINICAL TRIAL MAGNIFIER SPEAKER

KC LAU, PhD, PPD

Hong Kong-China

Nov 13, 13:15 – 13:35

Clinical Trial Players and Responsibilities

ABSTRACT

Countries in Asia have been increasingly involved in global product development programs of pharmaceutical and biotech companies. In the last 10 years the number of global studies conducted in Asia has increased significantly and this trend is expected to continue in the future. These studies conducted in Asia have to fulfill the regulatory standard as required by the Western regulatory bodies as a minimum to comply with the ICH GCP. ICH GCP has detailed the responsibilities of different players involved in the conduction of clinical trials. The author will briefly discuss the players involved in clinical trials and their responsibilities.



BIBLIOGRAPHY

KC Lau, PhD, joined PPD in 2002 as Director of Clinical Management – Northeast Asia. He is responsible for the management and completion of projects and for line management of clinical operations staff in Hong Kong, China, Taiwan, South Korea and Japan. He provides administrative, clinical, and fiscal guidance to team members. Prior to joining PPD, Dr. Lau was a clinical research manager for ProPharma Asia Ltd.; clinical services manager and lead clinical research associate for Quintiles Hong Kong Ltd; and a clinical research associate for Roche Hong Kong Ltd. Dr. Lau holds a doctorate in neuroscience from The University of Hong Kong. He is proficient in Mandarin, Cantonese and English.

CLINICAL TRIAL MAGNIFIER SPEAKER

Chaya MAZOUZ, BSc, RN, MA

Haifa-Israel

Nov 13, 13:35 – 13:55

Communicating with Regulatory Authority

ABSTRACT

Though science remains the fundamental impellent behind a successful new drug application, effective communication between companies and regulatory authorities at each stage of the development process stands as an essential element in securing approval for any suggested therapy.

Applicant companies that frequently gain approval and avoid delays, practice not only good science but also cultivate and maintain strong working relationships with the authorities and its personnel.

There are many reasons for interaction with the authorities during the development of a new product. Usually, by the first contact, you have already expended a significant amount of time and funds, therefore you should be prepared. Remember, the authorities want you to succeed; they are trying to be helpful; however they are the patients advocate and have a mandate to both protect and promote public health. There are specific standards that must be met to address regulatory concerns, but they are willing to discuss how to successfully address those concerns in order for your product to be tested in the clinic.

It is essential to demonstrate that your clinical development program is safety oriented and that due care and thought had gone into preparing your, non-clinical, manufacturing and clinical plans.

The authorities are data driven; stick to the facts. Most people have a tendency to go overboard in their enthusiasm to share their knowledge, do not do this! It annoys the authorities.

In Pluristem's phase I clinical studies, utilizing for the first time, mesenchymal-like stromal cells derived from a placenta, termed PLX-PAD for the treatment of critical Limb Ischemia; we were privileged to exercise a fruitful communication relationship with the regulatory authorities both in the U.S. and Germany, which permitted the company to enter clinical trials in the most efficacious and time conserved manner.



BIBLIOGRAPHY

Chaya Mazouz currently holds the position of VP at Clinical and Regulatory Affairs for Pluristem Ltd., a bio-therapeutics company dedicated to the commercialization of allogeneic cell therapy products, derived from human placenta. Chaya is a certified nurse with a BSc and MA from the Hebrew University of Jerusalem. Prior to joining Pluristem, Chaya held the position of Clinical Operations Director for Medgenics, a clinical-stage biopharmaceutical company involving gene therapy, where she engineered Phase I/II clinical studies. Previously, Ms. Mazouz served as Clinical Manager for TransPharma Medical, a drug delivery company, where she was responsible for managing all of the company's clinical activities. In previous positions, Ms. Mazouz led a multi-center Phase II study for Pharmos, a pharmaceutical company, and was CRA and Project Manager at IDgene, a startup company engaged in gene discovery.

CLINICAL TRIAL MAGNIFIER SPEAKER

Kyung-Soo KIM, MD, PhD

Seoul-South Korea

Nov 13, 13:55 – 14:15

The Perfect Sponsor

ABSTRACT

According to ICH GCP Guidelines, the followings are the responsibility of the sponsor: Quality assurance/quality control, appropriate professional expertise, trial management, data, records, selection of investigators, communication with regulatory authorities, confirmation of site compliance with regulatory requirements, supply of investigational products, monitoring of sites and reporting. From the investigative site's perspective, clinical trials are characterized by demanding protocols, tough deadlines, grant payment problems, and enrollment pressures where a majority of difficulties are caused by the sponsor. But from the sponsor's point of view, there are so many challenges to overcome, namely patent expirations, intense global competition, and heightened emphasis on safety. So the subject of improving sponsor-site relations as a way to improve performance has been a topic of discussion for long time. To re-introduce the human element and essentially upgrade the relationship between sponsors and sites, a number of sponsors are engaging in initiatives to figure out exactly what sites want in the way of a relationship. In my opinion, the perfect sponsor in a clinical trial can be defined as one who does one's best to support the investigator/institution involved in the study from the beginning to the end according to ICH GCP Guidelines. Such a supportive commitment of perfect sponsors is well expressed in the 'agreement' for the clinical study. The clinical-trial agreement defines the boundaries of researchers' and industry sponsors' rights and obligations. The clinical-trial agreement is the critical regulator of threats to academic freedom, with the potential to induce researchers' compliance with a sponsor's demands or to protect researchers from them. Standards for certain restrictive provisions in clinical-trial agreements with industry sponsors vary considerably among academic medical centers. Further consensus-building between investigative site and sponsor for ethical as well as productive research partnership is necessary.



BIBLIOGRAPHY

Dr. Kyung-Soo Kim was born in 1960 and graduated from School of Medicine, The Catholic University of Korea in Seoul of 1985. He earned his master's degree in the field of occupational medicine from Graduate School of Occupational Health in 1992 and Doctor of Medical Science in the field of pharmacology from Catholic University Graduate School, also from The Catholic University of Korea in 1996. He acquired Family Medicine Board Certification and Occupational Medicine Board Certification in 1988 and 1993, respectively.

From 1998 to 2000, he studied abroad in the Department of Clinical Pharmacology, Vanderbilt University, Tennessee, USA as a Research Fellow. In regards to his current professional experiences and positions, he is working actively as a Member of Advisory Board, KFDA; Vice President of Korean Society for the Study of Obesity; Director of Clinical Trial Center, Seoul St. Mary's Hospital; President, Korean Associate of Clinical Trial Centers to name a few examples. He has academic membership in Korean Society for Clinical Pharmacology and Therapeutics, Korean Society for the Study of Obesity, The Korean Academy of Family Medicine and American Society for Clinical Pharmacology and Therapeutics. His research interests include obesity, metabolic syndrome, pharmacogenetics and clinical nutritional science.

CLINICAL TRIAL MAGNIFIER SPEAKER

Vikram GOTA, MBBS, MD

Mumbai-India

Nov 13, 14:15 – 14:35

The Wonderful Investigator

ABSTRACT

The ICH GCP describes an investigator as 'A person responsible for the conduct of the clinical trial at a trial site'. The definition is over simplistic as it gives no idea about the criticality of his role in the successful conduct of a clinical trial. The investigator occupies a central position around whom the entire framework of the trial is constructed. He is the point of contact for the trial subjects, the trial sponsor and the ethics committee alike. He is responsible for the management and integrity of the design, conduct, and reporting of the trial. Additionally, the investigator is responsible for the direction and oversight of compliance, finance, personnel, and other aspects related to conducting a trial. He can delegate duty but not responsibility. In that sense, he is omnipresent in the clinical trial landscape. He ensures that the trial is conducted in accordance with the principles of GCP, the protocol and the regulatory requirements. It is not without reason, therefore, that he richly deserves the tag – 'The Wonderful Investigator'. The travails and ecstasy, ups and downs in the life of an investigator will be discussed in the talk.



BIBLIOGRAPHY

Dr. Vikram Gota is an Assistant Professor of Clinical Pharmacology at the Advanced Centre for Treatment, Research and Education in Cancer (ACTREC), Tata Memorial Centre, Mumbai, India. He is a clinical pharmacologist by training. Dr. Gota completed his Doctor of Medicine (MD) in pharmacology from the Christian Medical College, Vellore, India in 2005 and his post-graduate diploma in clinical trials (PGDCT) from the London School of Hygiene and Tropical Medicine (LSHTM), University of London, in 2008. His research and academic interests include design and conduct of early phase clinical trials in cancer, pharmacokinetics of anticancer drugs in Indian pediatric patients, and to start training programs in clinical research for young investigators in India. Dr. Gota has been an investigator for several early phase (Phase I, II) clinical trials in cancer sponsored by the pharmaceutical industry as well as investigator initiated trials. He has presented his research work in several national and international conferences. Dr. Gota was awarded the best paper in the southern Regional Conference of Pharmacologists held at Kochi, India, in 2004. He has five publications in indexed journals. Dr. Gota is a life member of the Indian Society of Clinical Research (ISCR).

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CLINICAL TRIAL MAGNIFIER CHAIR

SESSION: SATELLITE SYMPOSIUM I

Chairperson: Nov 13, 15:10 – 15:55

Yuji KUMAGAI, MD, PhD

Yuji KUMAGAI, MD, PhD

Tokyo–Japan



Dr. Yuji Kumagai, a clinical pharmacologist, graduated from Medical College of Oita in Japan. After he received his formal training in clinical pharmacology, specifically in cardiac medication in Post Graduate School, also from the Medical College of Oita, he was sent to Dr. Franz Halberg's Chronobiology Laboratories at the University of Minnesota as an official trainee of the Japanese Society of Clinical Pharmacology and Therapeutics. There, he designed several chronopharmacological studies utilizing ambulatory blood pressure monitoring and Hotter ECG.

He is currently a professor in the Department of Pharmacology, School of Medicine at Kitasato University, and is also Director of the Clinical Trial Center at Kitasato University East Hospital.

He is a board member of the Japanese Society of Clinical Pharmacology and Therapeutics and a council member of the Japanese Pharmacological Society, and a board certified supervisor of Clinical Pharmacologists. He is a representative of the Japanese Society of Clinical Pharmacology Studies, which focuses on early clinical trials.

CLINICAL TRIAL MAGNIFIER SPEAKER

Ruiwen ZHANG, MD, PhD, DABT

Birmingham–United States

Nov 13, 15:10 – 15:55

The Importance of Clinical Pharmacology in Clinical Trials

ABSTRACT

With recent advances in the understanding of molecular and genetic basis of human diseases and increasing number of novel therapeutic agents entering clinical trials, there is an increasing need for better clinical trials, especially in the early phases. Clinical pharmacology plays a major role in almost every stage of preclinical and clinical evaluation of novel therapeutic agents and novel regimens of existing agents. In this presentation, three areas of research will be emphasized: 1) clinical pharmacology studies in preclinical drug discovery and development; 2) clinical pharmacology in early phase of clinical trials (phase 0 and phase I trials) and 3) pharmacogenetics and pharmacogenomics. Examples will be given in the area of cancer chemotherapy.



BIBLIOGRAPHY

Ruiwen Zhang, MD, PhD, DABT, is Professor of Clinical Pharmacology, Pharmacology and Toxicology and Director of Cancer Pharmacology Laboratory at the University of Alabama, Birmingham (UAB). He also is Senior Scientist in the UAB Comprehensive Cancer Center, Center for Aging, Center for AIDS Research, Chemoprevention Center, Gene Therapy Center, and Clinical Nutrition Research Center. With over 20 years of experience in the field of biomedical research, Dr. Zhang has more than 10 US patents and patent applications and has published more than 150 original papers, 2 books, and more than 50 invited reviews/book chapters. He has been an invited speaker for more than 70 occasions. Dr. Zhang is also a member of Winship Cancer Institute, Emory University School of Medicine, Atlanta, GA, and a Guest or Honorary Professor of several Universities in China. Dr. Zhang is an Editor, Associate Editor or Editorial Board Member of more than 10 scientific journals. He is a certified toxicologist by the American Board of Toxicology (DABT). Dr. Zhang has been a voting member/consultant of US FDA Medical Devices Advisory Committee. Dr. Zhang's expertise includes: pharmacology and therapeutics, drug discovery and preclinical drug development, clinical pharmacology and clinical drug development, cancer biology and molecular therapy, toxicology, clinical toxicology and clinical chemistry, nutraceuticals, cancer therapy, genetic therapy, cancer early detection, cancer prevention, and occupational and environmental medicine. Dr. Zhang has extensive experience in training graduate and post-graduate students and clinical investigators.

CLINICAL TRIAL MAGNIFIER CHAIR

SESSION: SATELLITE SYMPOSIUM II

Chairperson: Nov 13, 15:10 – 15:55

Edmund S TSUEI, BSc, MSc, PhD

Edmund S TSUEI, BSc, MSc, PhD

Sydney–Australia



Dr. Edmund Tsuei received his undergraduate degree in the United States of America and his doctorate from the University of Sydney in 1980.

Based in Sydney, Australia, Ed has been working in the area of global drug development, conducting high quality clinical trials in the Asia-Pacific region since the mid 1980s. He has built up regional global drug development departments in Asia-Pacific first for Parke-Davis, then for Searle before joining Roche. He is currently Regional Head of Pharma Development Operations, Asia-Pacific-Africa at Roche Products Pty Limited, responsible for global drug development activities in the region. He is a frequent speaker in international conferences on drug development in Asia.

In addition to global drug development, Ed's personal research interest is in the areas of both theoretical and clinical pharmacokinetics and has published many papers in these areas.

CLINICAL TRIAL MAGNIFIER SPEAKER

Markus HARTMANN, PhD, MDRA

Trier-Germany

Nov 13, 15:10 – 15:55

The Impact of the EU Clinical Trial Directive 2001/20/EC

ABSTRACT

The coming-into-force of the EU Clinical Trial Directive in May 2004 marked a watershed for clinical drug research in Europe. Since, many clinical research professionals blamed the directive to over-regulate and expose trialists to disproportional administrative burdens and costs. Perceived as a particular burden for non-commercial trials, stakeholders have forecasted a decline in clinical research activity in Europe. Five years after the directive came into force, several impact analyses have been issued. This satellite symposia aims to tell participants how Europe's actual regulatory framework is composed, to analyze the current situation for clinical research in Europe, and to provide an overview on the directive's outcomes.

It is widely recognized that the directive failed to harmonize trial requirements as intended. Increased administrative burdens and raised costs for trial management are repeatedly reported. On the other hand, ethics committees and national competent authorities adapted to tight timelines for ethical and regulatory approval, a requisite to raise the region's attractiveness for industrial trial sponsors. Regarding GCP compliance and patient safety, currently available benchmarks are not yet meaningful. The analysis of official clinical trial authorization statistics reveals that the directive resulted in leveling of trial activities from north and west to south and east Europe, rendering the latter destinations nevertheless more attractive for clinical trials.

As a whole, the number of authorized clinical trials is stagnating. Compared to other ICH regions (i.e. Japan and North America), the EU is losing ground in clinical research. Due to the situation, European policy makers announced now to reshuffle the regulatory as well as the legislative framework. The Voluntary Harmonization Procedure, a common mutual regulatory approval procedure open for applications since early 2009, is a first step towards a real centralized framework for the conduct of clinical drug trials.



BIBLIOGRAPHY

Dr. Markus Hartmann has been working since 2003 as an independent medical and regulatory affairs consultant. With well-grounded experience in anti-cancer drug development, his current professional activities range from project support for oncology product development to general regulatory intelligence consultancy.

Dr. Hartmann obtained his PhD in bioinorganic chemistry from the University of Heidelberg after graduate studies at Heidelberg, Toulouse University and the University of Kent at Canterbury – carrying out research on the mode of action of tumour-inhibiting metal complexes. After a post-doc in molecular biophysics at the French CNRS, he joined the CRO business sector (ICON Clinical Research), working in Belgium, France and Germany, and later on the pharmaceutical industry (Aventis Pharma), serving as project manager and medical advisor. From 2003 to 2005 he completed a master degree in Drug Regulatory Affairs at the University of Bonn, specializing in regulatory and legal issues impacting on clinical research (Master Thesis: Impact of EU Clinical Trial Directive on non-commercial clinical research: A cross-European analysis).

He is a member of the European Association for Cancer Research (EACR), German Cancer Society (DKG), European Forum Good Clinical Practice (EFGCP), and German Society for Regulatory Affairs (DGRA). He serves as a peer reviewer on clinical regulatory issues for the BMJ and PLoS Medicine.

CLINICAL TRIAL MAGNIFIER CHAIR

SESSION: SATELLITE SYMPOSIUM III

Chairperson: Nov 13, 15:10 – 15:55

Rodney GALE, BSc, DPhil, MBA

Rodney GALE, BSc, DPhil, MBA

London–United Kingdom



Rodney Gale has worked in contract research for over 35 years, in a variety of industries, and has a wealth of experience in estimating, pricing, negotiating and managing commercial contracts. He has a BSc and a DPhil in Physical Chemistry and an MBA from London Business School. For the past 10 years, he was the Director of Research Support at the Hammersmith Hospital, one of the most research active centres in the United Kingdom. He was responsible for research governance and managed a portfolio of biomedical research worth £100million per annum. He ran a commercial contract research unit that had an annual turnover of £2million and handled over 100 separate contracts in a wide range of specialties and with a large number of biomedical companies and contract research organisations.

Since May 2009, he has been continuing his work in biomedical research as a freelance management consultant. He runs in-house coaching and training in all aspects of trial management.

CLINICAL TRIAL MAGNIFIER SPEAKER

Ling SU, PhD

Shanghai–China

Nov 13, 15:10 – 15:40

Possible Clinical Research Professionals Career Pathways

ABSTRACT

In the past several years, there has been a significant increase in clinical trial activities in the Asia Pacific region with China being one of the most active countries. The number of clinical research professionals has also grown significantly. In the same time, many multinational pharmaceutical companies have set up R&D centers in China, bringing in other pharma R&D functions to the region, such as project and study management, clinical sciences, data management, biostatistics, safety reporting and processing, and medical writing. The expansion of R&D scope in China broadens the horizon and career prospect for clinical research professionals. This presentation will examine this trend and discuss, from an industry point of view, the potential career pathways and challenges for clinical research professionals in this dynamic market place.



BIBLIOGRAPHY

Dr. Ling Su is currently Vice President, Clinical Research and Development – Asia Pacific Research Organization in Wyeth, responsible for clinical development and research operations in the Asia Pacific region. He has 20 years of experience in the pharmaceutical industry and the regulatory agency, in both US and Asia, and in a variety of therapeutic/disease areas. He started his career in the 1980s working in the Bureau of Drugs of the Ministry of Health, the Chinese drug regulatory agency. He was a Visiting Scientist in the Center for Drug Evaluation and Research, US FDA, in 1992–1993. He joined Merck Research Laboratories (MRL), Merck & Co., in US in 1996 as an Epidemiologist, was the Medical Director for Merck Sharp & Dohme (China) in 2000–2002 and was Senior Director, Global Strategic Regulatory Development in MRL in 2003. Prior to his current position, he was the International Pharma Development Director and subsequently, the Medical and Pharma Development Director at Shanghai Roche from 2003 to June 2007. He received his BS degree in Clinical Pharmacology from Shanghai Medical University, China; and MS degree in Clinical Pharmacy and PhD in Epidemiology, both from the University of North Carolina at Chapel Hill, USA. His professional experience and interests encompass the fields of regulatory affairs, clinical research and development, R&D strategies, pharmacoepidemiology, and outcomes research. He currently serves on the Board of Directors of the Drug Information Association (DIA) and chairs the DIA Advisory Council of China. He is an adjunct professor at the College of Pharmacy, Fudan University in Shanghai, China.

CLINICAL TRIAL MAGNIFIER SPEAKER

Philip AU, MMedSc, MBA, RN, CIPM, CCRA

Hong Kong-China

Nov 13, 15:40 – 15:55

Possible Clinical Research Professionals Career Pathways – in the CRO Industry

ABSTRACT

Pending



BIBLIOGRAPHY

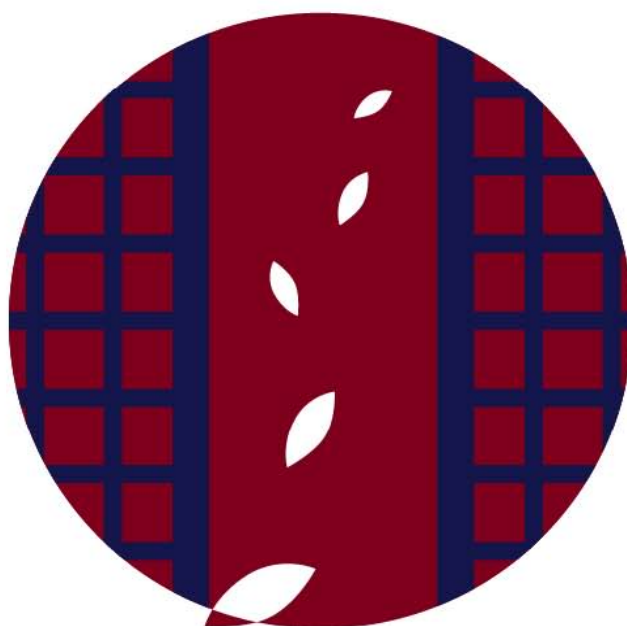
Philip Au is Associate Director of Project Management based in Hong Kong. As Project Director, he works closely with project managers to oversee the project management timelines and financial aspects.

For the past few years, he also worked for project management for global clinical trials from Phase I to IV for different therapeutic areas. Among oncology experience, he has managed a Phase I Hepatocellular Carcinoma study and a Phase IV Non-small Cell Lung Cancer study.

Prior to joining PAREXEL APEX, he worked 12 years for global pharmaceutical companies with sales and marketing experience in addition to CRA experience. This also enhances his full understanding in customer focus on the client's needs from clinical trials to product marketing authorization.

He is a member of Certified International Project Manager from American Academy of Project Management and certified Clinical Research Associate from Association of Clinical Research Professionals. He also is a registered nurse. He has obtained a Master Degree of Medical Science in Clinical Trials Research Methodology and a Master Degree in Business Administration.

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CLINICAL TRIAL MAGNIFIER CHAIR

SESSION: STUDY SITE MANAGEMENT – ESTABLISHED AND EMERGING TRIAL NETWORKS

Chairpersons: Nov 13, 16:00 – 18:00

Rodney GALE, BSc, DPhil, MBA

Jerome B ZELDIS, MD, PhD

Rodney GALE, BSc, DPhil, MBA
London–United Kingdom



Jerome B ZELDIS, MD, PhD
New Jersey–United States



Rodney Gale has worked in contract research for over 35 years, in a variety of industries, and has a wealth of experience in estimating, pricing, negotiating and managing commercial contracts. He has a BSc and a DPhil in Physical Chemistry and an MBA from London Business School. For the past 10 years, he was the Director of Research Support at the Hammersmith Hospital, one of the most research active centres in the United Kingdom. He was responsible for research governance and managed a portfolio of biomedical research worth £100million per annum. He ran a commercial contract research unit that had an annual turnover of £2million and handled over 100 separate contracts in a wide range of specialties and with a large number of biomedical companies and contract research organisations.

Since May 2009, he has been continuing his work in biomedical research as a freelance management consultant. He runs in-house coaching and training in all aspects of trial management.

Jerome B Zeldis is CEO of Celgene Global Health and Chief Medical Officer of Celgene Corporation, Summit, New Jersey. Prior to that he was Celgene's Senior Vice President of Clinical Research and Medical Affairs.

He attended Brown University for an AB, MS, followed by Yale University for an MPhil, MD and PhD in Molecular Biophysics and Biochemistry (immunochemistry). Dr. Zeldis trained in Internal Medicine at the UCLA Center for the Health Sciences and Gastroenterology at the Massachusetts General Hospital and Harvard Medical School.

He was Assistant Professor of Medicine at the Harvard Medical School, Associate Professor of Medicine at University of California, Davis, Clinical Associate Professor of Medicine at Cornell Medical School and Professor of Clinical Medicine at the Robert Wood Johnson Medical School in New Brunswick, New Jersey. Prior to working at Celgene, Dr. Zeldis worked at Sandoz Research Institute and Janssen Research Institute in both clinical research and medical development.

He has been a board member of a few start-up biotechnology companies and is currently on the board of the Semorex Corporation, New Jersey Chapter of the Arthritis Foundation and the Castleman's Disease Organization.

He has published 105 peer reviewed articles and 24 reviews, book chapters, and editorials.

CLINICAL TRIAL MAGNIFIER SPEAKER

Pyatat TATSANAVIVAT, MD

Bangkok–Thailand

Nov 13, 16:00 – 16:20

Clinical Research Collaboration Network (CRCN) in Thailand

ABSTRACT

Clinical Research Collaboration Network (CRCN) was established in 2000 under the joint support of the Consortium of Thai Medical Schools (CoTMeS), National Research Council of Thailand and Health System Research Institute. International Health Research Award of the Rockefeller Foundation was the start-up fund. It is a not-for-profit organization under the umbrella of the Medical Research Foundation to pursue its mission: create and strengthen multicenter clinical research capacity and management platform, to cope with the increasing public demand, locally and globally, of quality and evidence-based health care. Its sister networks are: Data Management and Biostatisticians Network (DMBN), the Network of Clinical Research Center of the CoTMeS, and Research for Quality (R4Q) – the joint network of CRCN and the Institute of Hospital Quality Improvement & Accreditation (HA). A customized data management program – Online Medical Research Tools (OMERET) is being developed and used. After almost a decade, the number of investigator-initiated multicenter clinical research projects has remarkably increased, particularly focusing on common and important problems. A few examples are: Survival of childhood cancer in Thailand; Anesthesia Related Adverse Events in Thailand (THAI-study); Outcome of invasive cervical cancer at university hospitals and regional cancer center in Thailand; Chronic viral hepatitis B treatment and outcome; Registries: Stroke Registry; Acute coronary syndrome. Clinical practice guidelines have been modified as resulted from new data. Currently, CRCN provides full services for locally funded multicenter clinical research and provides regulatory affairs, project monitor and data management services for industry-sponsored projects.



BIBLIOGRAPHY

After obtaining his MD from Chulalongkorn University, Thailand in 1975, Professor Pyatat Tatsanavivat pursued clinical specialist trainings and received a Diploma of Thai Board of Internal Medicine, in 1983; Diploma in Epidemiology (Clinical), Newcastle, Australia in 1990; and a diploma of Thai Sub-board of Cardiology, Thailand in 1992.

From 1997 to 2005, Professor Tatsanavivat was appointed as Associate Dean for Research Affairs, Faculty of Medicine, Khon Kaen University, Khon Kaen (two consecutive terms) and Chairman of Ethics Committee, Faculty of Medicine, Khon Kaen University.

During 2000 to 2002, he was a board of trustees member of the International Clinical Epidemiology Network Trust (INCLEN Trust International Incorporation); a Regional Coordinator, International Clinical Epidemiology Network – Southeast Asian (INCLEN – SEA); an Academic Task Force for the National Health System Reform, Thailand.

Professor Tatsanavivat currently holds a position as Head of the Cardiovascular Unit at the Department of Medicine; a program director of PhD in Clinical Sciences Program, Faculty of Medicine, Khon Kaen University; Director of Clinical Research Collaboration Network (CRCN), a network of the Consortium of Thai Medical Schools and Health System Research Institute; and Director of Medical Research Foundation (MRF), Thailand.

CLINICAL TRIAL MAGNIFIER SPEAKER

Peter OBEROSLER, PhD

Munich–Germany

Nov 13, 16:20 – 16:40

Utilization of Trial Networks

ABSTRACT

Networking is a very powerful tool to enhance the performance of clinical trials. Networking can be carried out in different layers of a research study. Omitting a network of researchers (e.g. physicians) interested in special indications may lead to underperformance in terms of enrolment rates. On the other hand, a network of CROs working in different regions of the globe with in-depth local knowledge, can significantly impact the enrolment figures as well as the quality of data. Local CROs often have very detailed knowledge of the local environment, thus being able to select the best performing sites with less conflicting trials. Based on that, it might be of great value for Pharma or Biotech companies to build networks with CROs leading to efficient and productive cooperation, and finally to the delivery of very good results in the shortest period of time.

How can we become involved in such networks? Within the Pharma environment, the best way to get to know networks on all different layers is congresses. Either specialized congresses on certain diseases or even on groups of indications like oncology can enhance the awareness of physicians' nets but also between Pharma companies and/or CROs. Regional congresses like CEE conferences are ideal to get connected to existing networks in specific regions. Additionally, literature research will provide information on research networks. In any case the local knowledge is the key for success.



BIBLIOGRAPHY

Dr. Oberosler graduated with a degree in molecular biology in 1993. After receiving his PhD from the University of Munich at the Max-Planck-Institute in 1996, he started his career in clinical research at Bristol-Myers Squibb as a CRA. After gaining in-depth insight into clinical trials, he moved on to a management position at PPD where he worked as a line manager and later country manager in a number of countries for 8 years.

Since a year and a half ago, he assumed responsibility as COO at Harrison Clinical Research, heading Clinical Operations, Biostatistics, Medical Writing and a Phase I/IIa clinic in Germany and CEE.

Over the years Dr. Oberosler gained extensive experience in clinical research from different perspectives through supervising and managing department and country managers, strategically developing areas of his responsibility (e.g. clinical research in Poland, Czech and Slovak Republics, Ukraine, Russia and Germany), and working on business development.

He is particularly interested in increasing clinical research in the CEE region but also interested in making Phase I/IIa studies more attractive in Germany.

CLINICAL TRIAL MAGNIFIER SPEAKER

Dongho LEE, MD, MBA

South Korea

Nov 13, 16:40 – 17:00

Korea National Enterprise for Clinical Trials (KoNECT)

ABSTRACT

In 2002, the Korean Ministry of Science and Technology initiated the National Technology Roadmap Project for Long-Range Strategy building. "Clinical Trial Technology" was one of the issues proposed to improve the country's ability to develop new medicines and biologicals in Korea. Practical recommendations were made to support the establishment of clinical centers of excellence to serve as state-of-the-art facilities for clinical trials and to develop training and educational programs for human resources based on a new paradigm. The biggest initiative was the "Regional clinical trial center supporting program", by the Ministry of Health in 2004, based on the 2002 National Roadmap Report.

In December 2007, the Korean Ministry for Health, Welfare and Family Affairs (MIHWFA) expanded governmental support to include trial-related professional human resources and new innovative technology development in clinical trials into the existing Regional Clinical Trials Center (RCTC) program, which was initiated in 2004, and gave birth to a new organization named KoNECT, the Korea National Enterprise for Clinical Trials.

KoNECT currently supervises and coordinates a network of 14 Regional Clinical Trial Centers, develops and operates training programs for trial specialists and supports and guides new development of technology in an effort to maximize impact and dynamize synergy among infrastructure, human resources, and technology.

Through these, KoNECT has shown remarkable achievement to bring up clinical trials, not only by quantity also by quality for last 2 years.



BIBLIOGRAPHY

Dr. Dongho Lee is Executive Director of the Clinical Research Center at Asan Medical Center (AMC).

He joined the center in July, 2007 and in this position, he is responsible for the global leadership, business development and management of clinical trials led by AMC.

He concurrently serves as Vice President of KoNECT (Korea National Enterprise for Clinical Trials), a representative body of the Korean government to support clinical trials in Korea. As a key opinion leader, he leads the clinical trial area in the country by setting up goals and establishing long-term strategic relationships with government, academia and industry.

Prior to this, he worked as Medical Director at GSK for three and a half years in Korea since 2001 and then moved on to the local pharmaceutical company, Samyang Corporation, where he spent 3 years to take up the pharmaceutical part of the company as Head of Pharmaceuticals BU.

Before joining the pharmaceutical industry, he worked as Faculty in the Department of Anesthesiology at Hanyang University Hospital for 14 years after finishing his fellowship and residency at Seoul National University Hospital from 1983 through 1987. Between 1993 and 1994, he worked at Yale University as a Visiting Professor.

He received his MD at Seoul National University in 1979 and also obtained an MBA degree from Korea University in 2006.

CLINICAL TRIAL MAGNIFIER SPEAKER

Teck-Onn LIM, MD

Kuala Lumpur-Malaysia

Nov 13, 17:00 – 17:20

Clinical Research Centre (CRC) in Malaysia

ABSTRACT

The Clinical Research Centre (CRC) is one of the six research institutes under the National Institute of Health Malaysia (MOH). The CRC functions as the clinical research arm of the MOH. Apart from our broad public health research mission to improve patients' health outcomes through ethical and quality clinical research, we are also tasked with promoting the contract Clinical Research Industry in Malaysia, particularly through tapping into the vast network of public hospitals and clinics as a rich ground to recruit investigators and enroll patients for industry sponsored clinical trials.

The industry has grown rapidly, especially in recent years with increasing off-shoring of clinical trials from its traditional locations in US and Europe to emerging markets, including those in Asia. Malaysia has several strengths including our clinical trial savvy and English speaking clinical investigators, well developed medical infrastructure, large patient population accessible through the vast network of public healthcare facilities, robust regulatory environment, strong Government commitment and support for the industry and last but not least, our relatively lower cost. Hence, industry sponsored trials have more than doubled in number from about 40 to 60 trials a year in the past decade to 172 in 2008 (124 in 2009 to date); and the number of sites recruited have grown to 350 in 2008 targeting enrolment of about 5,000 patients.

For clinical research to reach new heights in the Asian region, we believe collaboration among individual organizations with responsibility for clinical research within each national jurisdiction will be crucial. We look forward to developing mutually beneficial relationship with our counterparts in the Asian region.



BIBLIOGRAPHY

Dr. Lim Teck Onn is the Director of Clinical Research Centre, Ministry of Health, Malaysia, a Consultant Nephrologist at Department of Nephrology Kuala Lumpur Hospital, and an Adjunct Professor at International Medical University. He obtained his MRCP, UK in 1988 and FRCP, Edinburgh in 2000. Apart from his medical qualifications, Dr. Lim also has a Master in Medical Statistics from the University of Newcastle, Australia. Throughout his career he has been actively involved in clinical research.

He has more than 50 research publications, mostly in reputable international journals. His paper entitled "Assessing Doctors' performance: Application of CUSUM technique in monitoring doctor's performance. International Journal of Quality in Health Care 2002; 14:251-8" was nominated as best paper published for the Peter Reizenstein Prize, a first for Malaysia in association with the journal.

Dr. Lim has been a WHO Consultant for GCP in Clinical Trial (2002- 2003) to China (TCM Research Institute Beijing), consultant on Clinical Research and GCP to the Aga Khan University (2005 and 2006), University Medical Centre HCM & MOH Vietnam (2007, 2008), Ministry of Health Brunei (2007, 2008), King Saud University College of Medicine Saudi Arabia (2009).

He is an editor of the journal "Nephrology", and sits on the Editorial Advisory Board of the journal "Monitor".

CLINICAL TRIAL MAGNIFIER SPEAKER

Shyard WONG, MBBS

Singapore

Nov 13, 17:20 – 17:40

Optimizing Partnerships between Public and Private Organizations in Driving Clinical Research

ABSTRACT

Pending



BIBLIOGRAPHY

Having graduated from the National University of Singapore in 1991 and subsequently rotated through a series of clinical postings as a medical officer with the Ministry of Health including two years of Emergency Medicine, Dr. Shyard Wong went on to join a private hospital in Singapore as a resident doctor in 1997 and was then promoted to chief resident in 1999 where he was also in charge of outpatient services. Dr. Wong then undertook a career switch to become a full-time health administrator in National Healthcare Group, one of the two healthcare clusters in Singapore, overseeing the development of clinical programs across the continuum of patient care as well as in the administration of research and development.

In 2006, he joined Sanofi-aventis as a Medical Advisor of the South East Asia Clinical Research Unit and subsequently took over as Director of the unit in 2008 overseeing the IND Trial operations in Malaysia, Hong Kong, Indonesia, Philippines, Singapore, Taiwan and Thailand.

CLINICAL TRIAL MAGNIFIER CHAIR

SESSION: PROJECT MANAGEMENT AND MONITORING – THE BASICS

Chairpersons: Nov 13, 16:00 – 18:00

Frank FAN, MD, MBA

Jing-Ping YEO, PhD

Frank FAN, MD, MBA
Hong Kong-China



Jing-Ping YEO, PhD
Singapore



Dr. Fan is the Medical Director of Wyeth Hong Kong Limited.

Dr. Fan holds a Medical Degree from Capital University of Medical Sciences, Beijing, China. He practiced orthopedics and rheumatology for six years prior to joining the pharmaceutical industry in 1994.

Dr. Fan has conducted clinical research in the therapeutic areas of inflammation /immunology, infectious diseases, diabetes, gastroenterology and oncology. He successively held the leadership positions of clinical research and medical affairs in the global pharmaceutical companies in the past 10 years.

Dr. Yeo has a track record of 13 years of experience in pharmaceutical industry clinical research. She has just made a drastic transition a few months ago by joining the largest CRO in the region to further develop her career. In her current capacity, she manages a team of project managers to ensure the timely and high quality delivery of projects as requested by the sponsor. She is heavily involved in the review of proposal development for new outsourcing requests by sponsors. She is also the primary liaison with the sponsors to maintain partnership.

Dr. Yeo started her career with Novo Nordisk in 1997 as a medical writer – of which she is probably the first of a handful of people based in Singapore to be in this profession. Since then, she has gained experience in leading clinical research groups of multi-disciplinary experts – including biostatisticians, medical writers, clinical research managers and clinical quality managers. Her past experience also includes planning and management of trial allocations from headquarter to the region and resource management.

CLINICAL TRIAL MAGNIFIER SPEAKER

Soo-Yeon PARK, BSc

Seoul-Korea

Nov 13, 16:00 – 16:20

Essence of Project Management Skills

ABSTRACT

Everybody has a different perception of project management. Even project management positions within clinical research have variations with regards to local or international scope, the responsibilities of registration and database, deadlines, budget, experience and personal development. Within a clinical trial, there are different types of project managers depending on whether it is a global, regional or local level. However, the basics of successful project management are the same in terms of the necessary skills and knowledge in managing finance, people, work and time.

Project managers need to be well aware of the relevant activities required at each stage and have the abilities to interface with matrix partners globally or locally to obtain the support on time. These key activities need to be clearly communicated with each team member, who should also understand the exact communication plan during the ongoing project. With clinical trials spread across multiple investigator sites and potentially hundreds of patients enrolled, the project team needs to know the progress of their clinical trials in order to make faster, smarter decisions. For this, many companies provide study teams with a near real-time summary of a trial's progress globally and locally. This study progress report is extremely useful to save time and effort invested in gathering key data points to determine if a trial is on track or not.

For successful project management, not only the milestone achievement but also the quality management need to be carefully monitored and it would be better to put systemic quality control program in place.

More importantly, the trust and team effort need to be developed with matrix partners to optimize the likely success of projects by continuously learning and sharing.



BIBLIOGRAPHY

Soo-Yeon Park has 17 years of experience within the pharmaceutical industry, mainly within the clinical research environment.

Her current position is Senior Clinical Research Manager at GlaxoSmithKline (GSK) where she provides oversight for various global clinical studies conducted in Korea.

Previously within GSK, Soo-Yeon worked as Clinical Quality Manager, where she was responsible for managing clinical quality and a clinical operation manager, and was also responsible for facilitating clinical research.

Before joining GSK, Soo-Yeon worked as CRA at Marion Merrell Dow and Handok Pharm. She obtained her BSc in Pharmacy in Duksung University, Seoul and is a member of the Korea Society of Clinical Trial.

CLINICAL TRIAL MAGNIFIER SPEAKER

Emily TAN, MSc

Singapore

Nov 13, 16:20 – 16:40

Selecting Responsible Monitors

ABSTRACT

A monitor is traditionally defined as a person designated by the sponsor, with documented appropriate training, as responsible for overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, SOPs, GCP, and the applicable regulatory requirements.

Traditionally the monitor is the primary communication link between the sponsor and the Investigator. According to ICH GCP, a monitor has the responsibility of:

- verifying that the rights and well-being of human subjects are protected.
- verifying that the reported trial data are accurate, complete, & verifiable from source documentation.
- verifying that the conduct of the trial is in compliance with the currently approved protocol/amendment(s), with good clinical practices, and with applicable regulatory requirement(s).

However, in recent years, we see greater sub-specialization of monitor's role in the industry, for example, separately study start up activities and separating 'on-site' versus 'in-house' monitor roles.

The two main forces driving these changes include creating greater efficiencies in the clinical trial process with a bid to shorten timelines and lower cost and creating additional career ladders for monitors.

The disadvantages with these trends include: downgrading the importance of SDV, creation of silos will result in risk of information not being communicated across different groups, and knowledge being lost in the process. In addition, the future generation of monitors have a narrow scope of experience and limited exposure to the full spectrum of the clinical trial process.



BIBLIOGRAPHY

Emily is a registered pharmacist in Singapore and has a master's degree in Epidemiology from the University of London. She is currently Director of Clinical Research at Pharmanet, responsible for line and project management for the Asia region. She has worked in many therapeutic areas, with particular strength in oncology.

Emily was a hospital clinical pharmacist prior to joining the pharmaceutical industry in 1997. In the last 12 years, she has held progressive responsibilities in various large pharmaceutical companies. Her scope of responsibilities include scientific feasibilities, project management, process improvement, resource planning and providing clinical input into product brand planning. She has conducted many training workshops and lectures in clinical research.

Prior to joining Pharmanet, Emily spent eight years in Pharmacia/ Pfizer, where she was head of clinical research for Pfizer Singapore and Malaysia. She also spent one year at the Pfizer R&D Center in Shanghai, China, where headed the SOP, Training and Process implementation department for the Asia.

CLINICAL TRIAL MAGNIFIER SPEAKER

Peng CHAN, BSc (Hons)

Singapore

Nov 13, 16:40 – 17:00

Key Monitoring Roles and Responsibilities

ABSTRACT

In this session, key aspects of monitoring roles and responsibilities will be shared. They include: (1) protocol and GCP compliance, i.e. informed consent and study conduct; (2) good documentation practice and maintenance, i.e. source documentation and Investigator Trial File; and (3) source data verification, i.e. accurate, complete and timely data.



BIBLIOGRAPHY

Having graduated (BSc Hons) from University of Leeds, Peng first became involved in clinical trials as a Trial Coordinator in Singapore General Hospital in 2000. After overseeing the implementation of 3 Phase III Leukemia studies, Peng joined Novo Nordisk Asia Pacific International Operations Clinical Development Centre (IOCDC) in Singapore to be a Clinical Research Associate (CRA) in 2001.

During his years in IOCDC Singapore, Peng rapidly progressed from a CRA to a Clinical Project Manager. In 2007, he stepped up to an International Trial Manager role for a global Phase III study in Novo Nordisk's headquarters in Denmark.

Peng has extensive experience in managing clinical trials, having spent the last 7 years in project management of various therapeutic areas ranging from diabetes, hematology, emergency medicine, neurosurgery and cardiac surgery. Having worked in South Africa and Denmark and managing studies in global and Asia-Pacific region also provided Peng with the opportunity to lead and work with multi-cultural and multi-national teams.

At the end of 2007, Peng left Novo Nordisk during a restructuring exercise and founded Research2Trials Clinical Solutions, a boutique clinical research organization offering Data Management, Biostats and Medical Writing services in spring of 2008.

CLINICAL TRIAL MAGNIFIER SPEAKER

Daniel LI, BSc (Hon)

Hong Kong–China

Nov 13, 17:00 – 17:20

Proficiency in Writing Monitor Reports and Follow-up Letters

ABSTRACT

It is an ICH GCP requirement 5.18.6 to submit a written report to the Sponsor after each trial-site visit or trial-related communication. Reports should include the date, site, name of monitor and the name of investigator/other individual(s) contacted. Reports should include a summary of what was reviewed and the monitor's statements regarding the significant facts/findings, deviations and deficiencies, conclusions, actions taken or to be taken and/or actions taken to secure compliance. Meanwhile, follow-up letter should be sent to the investigator concerning actions and issues, agreements and key discussions which took place during the monitoring visits. This letter is extremely important as it documents the ongoing education and training of the study team during the study.



BIBLIOGRAPHY

Daniel graduated from the University of Toronto, Canada with double majors in Human Biology and Statistics. He is currently the Department Head of the Clinical Operation, PAREXEL APEX (H.K.) Co. Ltd., supervising more than 20 Clinical Research Managers (CRM), Clinical Leads and Clinical Research Associates (CRA). In 2008, he has established the PAREXEL APEX clinical operation in Guangzhou, China. With over eight years of experience in the clinical research industry, Daniel has participated in more than 40 phase I–IV clinical trials in different therapeutic areas. Moreover, he is actively involved in many multinational clinical trials as project manager in the Asia-Pacific region.

CLINICAL TRIAL MAGNIFIER SPEAKER

Yuji KUMAGAI, MD, PhD

Tokyo-Japan

Nov 13, 17:20 – 17:40

Important Aspects of Site Interaction by Sponsor/CRO

ABSTRACT

From the standpoint of clinical trial sites, the activity of monitors and project managers is important to a sponsor or CRO. It is helpful and often indispensable for investigators to get accurate information of an investigational drug from a project manager with sufficient knowledge and experience. Such interaction may stimulate the investigators' motivation to promote the trial. Trial sites will welcome visits by a sponsor or CRO especially when the timing is appropriate – such as during the initial enrollment of subjects and during a time dedicated to the essential evaluation of subjects for better quality control of trials and management of subjects. Most CRCs in Japan think highly of monitors who visit the site at the right time and answer questions by CRCs promptly and correctly. Although there is a tendency for communication to be slightly slower and less frequent in the case of monitors from CROs because of their disadvantage, still there are an exceptional few who would be described as excellent monitors of CROs. An investigator often experiences times where queries for case records are difficult to understand and having a monitor's help is most ideal under those circumstances. The most important matter is that interaction between sites and sponsors/CRO depends on good human communication, even if a trial is business performed under an engagement. Building good relationships and respecting each other as partners are easy, but ever so important.



BIBLIOGRAPHY

Dr. Yuji Kumagai, a clinical pharmacologist, graduated from Medical College of Oita in Japan. After he received his formal training in clinical pharmacology, specifically in cardiac medication in Post Graduate School, also at the Medical College of Oita, he was sent to Dr. Franz Halberg's Chronobiology Laboratories at the University of Minnesota as an official trainee of the Japanese Society of Clinical Pharmacology and Therapeutics.

There, he made several chronopharmacological studies utilizing ambulatory blood pressure monitoring and Holter ECG. He is now a professor in the Department of Pharmacology, School of Medicine at Kitasato University, and is also the director of the Clinical Trial Center at Kitasato University East Hospital,

He is a board member of the Japanese Society of Clinical Pharmacology and Therapeutics and a council member of the Japanese Pharmacological Society, and a board certified supervisor of Clinical Pharmacologists. He is a representative of the Japanese Society of Clinical Pharmacology Studies, which focuses on early clinical trials.

CLINICAL TRIAL MAGNIFIER CHAIR

SESSION: REGULATIONS - HOT TOPICS

Chairpersons: Nov 14, 09:00 – 11:00

Vikram GOTA, MBBS, MD

Pyatat TATSANAVIVAT, MD

Vikram GOTA, MBBS, MD

Mumbai–India



Pyatat TATSANAVIVAT, MD

Bangkok–Thailand



Dr. Vikram Gota is an Assistant Professor of Clinical Pharmacology at the Advanced Centre for Treatment, Research and Education in Cancer (ACTREC), Tata Memorial Centre, Mumbai, India. He is a clinical pharmacologist by training. Dr. Gota completed the Doctor of Medicine (MD) in pharmacology from the Christian Medical College, Vellore, India, in 2005 and the post-graduate diploma in clinical trials (PGDCT) from the London School of Hygiene and Tropical Medicine (LSHTM), University of London, in 2008. His research and academic interests include design and conduct of early phase clinical trials in cancer, pharmacokinetics of anticancer drugs in Indian pediatric patients, and to start training programs in clinical research for young investigators in India. Dr. Gota has been an investigator for several early phase (Phase I, II) clinical trials in cancer sponsored by the pharmaceutical industry as well as investigator initiated trials. He has presented his research work in several national and international conferences. Dr. Gota was awarded the best paper in the southern Regional Conference of Pharmacologists held at Kochi, India, in 2004. He has five publications in indexed journals. Dr. Gota is a life member of the Indian Society of Clinical Research (ISCR).

After obtaining his MD from Chulalongkorn University, Thailand in 1975, Professor Pyatat Tatsanavivat pursued clinical specialist trainings and received a Diploma of Thai Board of Internal Medicine, in 1983; Diploma in Epidemiology (Clinical), Newcastle, Australia in 1990; and a diploma of Thai Sub-board of Cardiology, Thailand in 1992.

From 1997 to 2005, Professor Tatsanavivat was appointed as Associate Dean for Research Affairs, Faculty of Medicine, Khon Kaen University, Khon Kaen and Chairman of Ethics Committee, Faculty of Medicine, Khon Kaen University.

During 2000 to 2002, he was a board of trustees member of the International Clinical Epidemiology Network Trust (INCLEN Trust International Incorporation); a Regional Coordinator, International Clinical Epidemiology Network – Southeast Asian (INCLEN – SEA); an Academic Task Force for the National Health System Reform, Thailand.

Professor Tatsanavivat currently holds a position as Head of the Cardiovascular Unit at the Department of Medicine; a program director of PhD in Clinical Sciences Program, Faculty of Medicine, Khon Kaen University; Director of Clinical Research Collaboration Network (CRCN), a network of the Consortium of Thai Medical Schools and Health System Research Institute; and Director of Medical Research Foundation (MRF), Thailand.

CLINICAL TRIAL MAGNIFIER SPEAKER

Henry MILLER, MD, PhD

Stanford–United States

Nov 14, 09:00 – 10:00

PLENARY LECTURE: Current Trends in Regulation

ABSTRACT

At a time when drug development should have been spurred by the exploitation of powerful new technologies and by huge increases in R&D expenditures -- which tripled to more than US\$45 billion between 1995 and 2007 -- drug approvals by the FDA have been disappointing. The 18 new medicines approved in 2007 was the lowest figure in a quarter century, and the 2008 tally of 24 represents scant improvement. Current trends in regulatory policies and requirements are likely to cause further deterioration in drug R&D and approvals.

The imposition of additional regulatory requirements and changes in policy by both the legislative and executive branches of the U.S. government will increase further the time and costs of drug development, diminish competition and make fewer new products available. The increasingly risk-averse Congress has granted the US FDA additional powers that place new restrictions on the prescribing, distribution, sale and advertising of drugs; and at the same time, regulators have imposed new criteria in addition to safety and efficacy on drug developers in order to obtain even those limited approvals. These additional criteria include: (1) obligations of pharmaceutical company executives to ensure the integrity of the "global manufacturing chain" of their products; (2) post-marketing studies as a condition of approval; and (3) evidence that new drugs are not merely effective but are actually superior to existing therapies, a new standard that is often difficult and extremely costly to meet.



BIBLIOGRAPHY

Henry I Miller is an academic researcher and author. A physician and molecular biologist, from 1977 to 1994, he was at the US National Institutes of Health, and then the Food and Drug Administration (FDA). At the FDA, he was the medical reviewer for the earliest biopharmaceuticals and eventually became the founding director of the agency's Office of Biotechnology.

Since 1994, Dr. Miller has been a fellow at Stanford University's Hoover Institution, where his research focuses on the relationship between science and regulation, the costs and benefits of government regulation, models for regulatory reform, and federal and international oversight of biotechnology. He is the author of more than nine hundred articles in scholarly and popular publications and six books, including *To America's Health: A Proposal to Reform the FDA*. Barron's selected his most recent book, *The Frankenfood Myth: How Protest and Politics Threaten the Biotech Revolution* as one the 25 Best Books of 2004, and in 2006 he was listed by the editors of Nature Biotechnology as one of the personalities who had made the "most significant contributions" to biotechnology during the previous 10 years.

CLINICAL TRIAL MAGNIFIER SPEAKER

Suzanne GAGNON, MD, FACP

Pennsylvania–United States

Nov 14, 10:00 – 10:30

US FDA Inspections in Established versus Emerging Regions

ABSTRACT

The FDA's Bioresearch Monitoring Program (BIMO) is a comprehensive program for onsite inspections against GCP and GLP, established to ensure the quality and integrity of data for healthcare products market registrations. Each year FDA conducts approximately 1100 GCP inspections including investigators, IRBs, Sponsors/CROs, labs and other facilities. Inspections may occur anywhere in the world for clinical studies to be submitted to FDA. The Inspectors' focus is to ensure that the rights, safety and welfare of the subjects have been protected, that FDA regulations and statutory requirements have been adhered to, and to assess the quality and integrity of the data supporting the marketing application. Types of inspections include routine or for-cause audits. Strict adherence by an investigational site to GCP, keeping accurate records and adequate preparation in conjunction with the Sponsor or CRO increases the likelihood of a good outcome. The Inspector will interview study staff, inspect the test article storage area and audit study documentation. Documents inspected include administrative agreements, CRFs, ICFs and relevant clinical, hospital or research charts. Common deficiencies include protocol non-adherence, failure to report adverse events, inadequate drug accountability, and inadequate or inaccurate records. The Inspector will discuss any findings at an exit interview. An Establishment Inspection Report (EIR) is issued following the inspection. Compliance classifications include NAI – no action indicated VAI – voluntary actions indicated or OAI – Official FDA action indicated. Receipt of an FD-483 letter should be responded to in writing, specifically addressing the items of FDA's concern. Serious violations can result in the rejection of a clinical study, disqualification of an investigator or (rarely) prosecution of an investigator or Sponsor.



BIBLIOGRAPHY

Dr. Suzanne Gagnon – Chief Medical Officer & Executive Vice President, ICON Clinical Research

Dr. Suzanne Gagnon joined ICON in 2001 as Sr. Vice President of US Medical Affairs, Regulatory Affairs and Scientific Writing. In April of 2006, she was promoted to Global Head of Medical Affairs and Drug Safety, and in June 2008 she was named Chief Medical Officer.

Prior to joining ICON, she held various senior management positions in Medical Affairs and Clinical Research and Development at Rhone-Poulenc Rorer, Luitpold Pharmaceuticals and Omnicare Clinical Research. Her background includes eight years in academic medicine at Boston University, the University of Miami and as the Director of Clinical Research at the University of Kansas School of Medicine.

Suzanne received her medical degree from Boston University School of Medicine, is Board Certified in Internal Medicine and is a Fellow of the American College of Physicians. She has held a number of academic faculty appointments and has published articles and abstracts on drug safety and in therapeutic areas including HIV disease, chronic renal failure and oncology. She currently lectures in Pharmaceutical Produce Development and Drug Safety at West Chester University.

CLINICAL TRIAL MAGNIFIER SPEAKER

Ulf MALMQVIST, MD, PhD

Lund–Sweden

Nov 14, 10:30 – 11:00

Risk Management of First-into-man Trials

ABSTRACT

The purpose of clinical trials is to produce information about the effects and safety of drugs. First time in human (FTIH) studies is a key point in drug development, when results from animal studies for the first time are evaluated in man. These studies are small, time-lagged dose-escalation studies involving volunteer subjects. The primary objective is to investigate the safety and tolerability of a new drug, and the secondary objectives is to assess the pharmacokinetics and pharmacodynamics for further studies. The major challenge in FTIH studies is risk assessment and determining whether the risk is acceptable. This needs to be made on behalf of the participating subjects and society, and depending on the benefits, they do not necessarily have the same acceptable levels of risk. It is the clinical trial design that leads to acceptable risk for the subjects, and in the present presentation, this will be discussed.



BIBLIOGRAPHY

Ulf Malmqvist is Head of Operation of the Clinical Research and Trial Centre at Lund University Hospital in Sweden. He holds an MD, is a consultant in clinical pharmacology and has a PhD in physiology from Lund University. He has worked with clinical trials in early phases of drug development both in the industry and academia.

CLINICAL TRIAL MAGNIFIER CHAIR

SESSION: RESEARCH ETHICS – PRINCIPAL POPULATION

Chairpersons: Nov 14, 11:30 – 13:00

Simon DONELL, BSc, FRCS (Orth), MD

Markus HARTMANN, PhD, MDRA

Simon DONELL, BSc, FRCS (Orth), MD
Norwich–United Kingdom



Markus HARTMANN, PhD, MDRA
Trier–Germany



Simon Donell is a Consultant Orthopaedic surgeon and the lead for research in the Department of Orthopaedics at the Norfolk & Norwich University Hospital and Co-Chairman of the Norwich Musculoskeletal Research Group. He holds an honorary Professorship with the Medical School at the University of East Anglia. He is the Lead for Injuries and Accidents and Co-Lead for Musculoskeletal Disease for the Norfolk & Suffolk Comprehensive Local Research Network. He is Co-Editor of The Knee journal and a Specialist Advisor on the Interventional Procedures Programme for the National Institute for Health & Clinical Excellence (NICE).

His research interests cover the range of musculoskeletal disease in collaboration with other disciplines including; matrix metalloproteinases in articular cartilage and Dupuytren's disease, health technology assessments for the Department of Health on bone morphogenetic protein with the health economists in the School of Medicine UEA, studies on the outcome of various joint replacements funded by industry, commercially sponsored studies on the accelerated healing of fractures, clinical studies on patellar instability including new imaging techniques, and an educational programme to train novice surgeons and other healthcare workers in knee replacement.

Dr. Markus Hartmann has been working since 2003 as an independent medical and regulatory affairs consultant. With well-grounded experience in anti-cancer drug development, his current professional activities range from project support for oncology product development to general regulatory intelligence consultancy.

Dr. Hartmann obtained his PhD in bioinorganic chemistry from the University of Heidelberg after graduate studies at Heidelberg, Toulouse University and the University of Kent at Canterbury – carrying out research on the mode of action of tumour-inhibiting metal complexes. After a post-doc in molecular biophysics at the French CNRS, he joined the CRO business sector (ICON Clinical Research), working in Belgium, France and Germany, and later on the pharmaceutical industry (Aventis Pharma), serving as project manager and medical advisor. From 2003 to 2005 he completed a master degree in Drug Regulatory Affairs at the University of Bonn, specializing in regulatory and legal issues impacting on clinical research (Master Thesis: Impact of EU Clinical Trial Directive on non-commercial clinical research: A cross-European analysis).

He is a member of the European Association for Cancer Research (EACR), German Cancer Society (DKG), European Forum Good Clinical Practice (EFGCP), and German Society for Regulatory Affairs (DGRA). He serves as a peer reviewer on clinical regulatory issues for the BMJ and PLoS Medicine.

CLINICAL TRIAL MAGNIFIER SPEAKER

Marjorie A SPEERS, PhD

Washington–United States

Nov 14, 11:30 – 12:00

Accreditation of Human Protection Programs

ABSTRACT

As the research enterprise has grown and expanded worldwide, more attention has been focused on the quality and efficiency of oversight systems to protect research participants. Researchers and ethics committees must be able to demonstrate that they are following international standards for conducting research and protecting research participants. Accreditation is one mechanism recognized by sponsors to ensure that ethics committees, hospitals, universities, among others, adhere to international standards of human research protection and comply with local laws. In this presentation, the presenter will describe the trends that led to the initiation of an accreditation program and current efforts to accredit research entities. The standards used by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) will be discussed as well as the major findings of over eight years of accrediting organizations worldwide.



BIBLIOGRAPHY

Dr. Speers is the President and CEO of the Association for the Accreditation of Human Research Protection Programs (AAHRPP), which offers accreditation services globally.

Previously, she served at the National Bioethics Advisory Commission from 1999–2001, both as project director for a report on the research oversight system and as Acting Executive Director. Dr. Speers was Deputy Associate Director for Science at the Centers for Disease Control and Prevention (CDC) from 1995–2000. As the Deputy Associate Director for Science, Dr. Speers oversaw the human subjects protection program both for domestic and international research.

While at CDC, Dr. Speers held a variety of positions at CDC from 1988–1995: Director of the Division of Chronic Disease Control and Community Intervention, Chief of the Aging and Statistics Branch, and staff epidemiologist. Prior to joining CDC, she was a faculty member at the University of Texas Medical Branch and the University of Connecticut –Stamford.

Her research is focused in public health, primarily on prevention and health promotion. Dr. Speers received doctoral degrees in psychology and epidemiology from Yale University and bachelor's degree in psychology from Dickinson College.

CLINICAL TRIAL MAGNIFIER SPEAKER

Boleslav L LICHTERMAN, MD, PhD

Moscow–Russia

Nov 14, 12:00 – 12:30

Ethical Problems with Clinical Trials in Russia

ABSTRACT

Clinical trials in Russia are regulated by a Federal Law, “O lekarstvennykh sredstvakh” (“On pharmaceuticals”), adopted in 1998. They should be approved by the ethics committee of the Federal Service on Surveillance in Healthcare and Social Development of Russian Federation. However, the ethics committee is not independent since the Service is part of the Ministry of Healthcare and Social Development of Russian Federation. The recent activity of this central ethics committee will be presented and analyzed. Since ethics control of clinical trials is highly centralized, local ethics committees (at hospitals, university clinics and research institutions) are mostly decorative organs established for protection of clinical investigators and publication of trial results in international periodicals. Other problems of conducting clinical trials include conflicts of interest in industry-sponsored research with special reference to the issue of financial motivation of investigators and informed consent in situation of limited access to healthcare facilities.



BIBLIOGRAPHY

Boleslav L Lichterman graduated from Gorky State Medical Institute (USSR) where he got his MD degree in 1982. Then he specialized in neurosurgery and defended his PhD thesis on calculated outcome prediction of traumatic cerebral compression in 1988 at the Burdenko Neurosurgery Institute in Moscow. Since the very same year until May 2001 he had been working at the chair of pediatric neurosurgery of Russian Postgraduate Medical Academy in Moscow, combining clinical work with historical research.

Currently he is a senior researcher at the Institute History of Medicine of Russian Academy of Medical Sciences in Moscow. His habilitation thesis is dedicated to early history of neurosurgery (1920s–1930s). It was published as a book “Neurosurgery: Emergence of a Clinical Discipline” (Moscow, 2007). His current research is focused on a history of clinical neuroscience, history of Russian/Soviet medicine and medical ethics.

Since 1997 he has been working part-time as scientific editor of a Russian National medical periodical “Meditsynskaya Gazeta” where he published numerous articles on neurological, medico-historical and ethical problems. He also has several publications on Russian medicine and book reviews in the British Medical Journal (BMJ). Since 2008 he has been working part-time as an associate professor (docent) of the history of medicine at Russian Postgraduate Medical Academy.

CLINICAL TRIAL MAGNIFIER SPEAKER

Melody H LIN, PhD

Rockville–United States

Nov 14, 12:30 – 13:00

Research Ethics and Informed Consent

ABSTRACT

Dr. Melody H Lin will describe ethical issues in research involving human subjects and major ethical principles that govern research with human subjects.

Dr. Lin will emphasize the shared responsibilities of the Investigator, Ethic Committee, Institution, Sponsor and Regulatory Agencies for protecting human subjects in research. She will also discuss how research integrity and avoiding conflict of interest relate to human research protection.

Dr. Lin will describe the elements that the U. S. regulations require in the informed consent form. Dr. Lin will focus on how to structure the informed consent process to make the research subject's consent ethically and legally valid.

When children are involved in research, each child almost always should provide his/her assent if capable of doing so and may refuse to participate even if the parent has provided permission.

U.S. Federal Regulations for the protection of human subjects in Biomedical & Behavioral research provide for procedural flexibility as long as the procedures are ethically defensible. Dr. Lin will discuss as examples the criteria for waiving or altering informed consent and the criteria for waiving documentation of consent.

In summary, Dr. Lin's presentation discusses: (1) Researchers, institutions, sponsors and regulatory oversight agencies have shared responsibilities to protect human subjects; (2) Informed consent and assent are on-going processes, rather than a one-time event; (3) Conflicts of interest in human research can cause behavior that is not ethical, including scientific misconduct, and such conflicts should be avoided or appropriately managed.



BIBLIOGRAPHY

As Deputy Director of the Office for Human Research Protections – OHRP (formerly the Office for Protection from Research Risks – OPRR), Dr. Lin is responsible for the management of OHRP policy, personnel, and budgetary matters regarding biomedical and behavioral research at both the national and international level. Dr. Lin also serves as the Director, Office of International Activities at OHRP.

Dr. Melody Lin, a native of Taiwan, received a BS degree in Pharmacy, and is a Registered Pharmacist. She received her PhD in Microbiology/Immunology and conducted research at the George Washington University Medical Center and the National Cancer Institute, National Institutes of Health (NIH). Dr. Lin is a Captain in the US PHS Commissioned Corps. Previous OHRP/OPRR duties include serving as AIDS Coordinator, Chief of the Compliance Oversight Branch, and Director of Division of Human Subject Protections. She frequently is invited, by various organizations, to discuss changing landscapes of human subject protection and compliance oversight in clinical trials and federal perspectives relating to IRB issues. Captain Lin is a member of the Advisory Committee of the National Research Program in Genomic Medicine in Taiwan, is the US liaison to the National Council on Ethics in Human Research in Canada, and is a member of the Advisory Council in European Forum on Good Clinical Practice. Notably, she has organized in excess of one hundred conferences for OHRP/OPRR national workshops and scientific symposia.

CLINICAL TRIAL MAGNIFIER CHAIR

SESSION: OPERATION - GLOBALIZATION

Chairpersons: Nov 14, 14:00 – 16:00

Kyung-Soo KIM, MD, PhD

Ole M BECH, MD, PhD

Kyung-Soo KIM, MD, PhD

Seoul-South Korea



Ole M BECH, MD, PhD

Beijing-China



Dr. Kyung-Soo Kim was born in 1960 and graduated from School of Medicine, The Catholic University of Korea in Seoul of 1985. He earned his master's degree in the field of occupational medicine from Graduate School of Occupational Health in 1992 and Doctor of Medical Science in the field of pharmacology from Catholic University Graduate School, also from The Catholic University of Korea in 1996. He acquired Family Medicine Board Certification and Occupational Medicine Board Certification in 1988 and 1993, respectively.

From 1998 to 2000, he studied abroad in the Department of Clinical Pharmacology, Vanderbilt University, Tennessee, USA as a Research Fellow. In regards to his current professional experiences and positions, he is working actively as a Member of Advisory Board, KFDA; Vice President of Korean Society for the Study of Obesity; Director of Clinical Trial Center, Seoul St. Mary's Hospital; President, Korean Associate of Clinical Trial Centers to name a few examples. He has academic membership in Korean Society for Clinical Pharmacology and Therapeutics, Korean Society for the Study of Obesity, The Korean Academy of Family Medicine and American Society for Clinical Pharmacology and Therapeutics. His research interests include obesity, metabolic syndrome, pharmacogenetics and clinical nutritional science.

Dr. Mølskov Bech graduated from Medical Faculty, University of Copenhagen, Denmark in 1985. From 1985–1987 he held a position as Research Fellow at the Department of Pharmacology, University of Aarhus, with special focus on Clinical Pharmacology and a laboratory model of congestive heart failure. After postgraduate training at Hvidovre and Gentofte County Hospital (1987–1990), he joined Novo Nordisk in 1990 as Project Manager for a development project (LMW Heparin).

In 2002, Dr. Mølskov Bech obtained his MBA from Scandinavian International Management Institute, Copenhagen.

Dr. Mølskov Bech has been working in Asia since 2002, when he was appointed Medical Director, Novo Nordisk Asia Pacific. Since November 2003, Dr. Mølskov Bech has been responsible for the clinical development activities for Novo Nordisk in Asia Pacific, Latin America, Africa and Middle East, East and Central Europe, Australia and New Zealand. During this period the number of patients in clinical trials in the region has more than tripled to around 6000 patients per year.

Dr. Mølskov Bech is a member of Novo Nordisk Global Development Management Team.

CLINICAL TRIAL MAGNIFIER SPEAKER

Edmund S TSUEI, BSc, MSc, PhD

Sydney–Australia

Nov 14, 14:00 – 15:00

PLENARY LECTURE: The Role of Asia in Global Drug Development

ABSTRACT

The headroom for global drug development growth in Asia will be examined from the perspectives of pharmaceutical market potential as well as drug development potential.

Three of the world's top five economies are in Asia. Not counting Russia, seven of the world's top ten countries with the largest foreign currency reserves are in Asia. IMS forecasts projected that the Asia–Australia–Africa region to be the world's fastest growing pharmaceutical market in 2009, with a growth more than 3 times the global average. From a business perspective, Asia is a region that is likely to drive pharmaceutical market growth in the future.

From a drug development perspective, three of the world's top five most populous countries are located in Asia. With a large population, together with an increasingly westernized life style, Asia has the potential for fast patient recruitment into most clinical studies, shortening clinical development time and allowing fast access for innovative medicines to patients. Regulatory agencies in many Asian countries have taken steps to improve efficiency without sacrificing quality. Clinical trial approvals timelines are now competitive on a global basis in most countries.

There is a large pool of talented healthcare professionals in Asia to be involved in drug development activities. However, there is a shortage of experienced staff to satisfy the growing demand for talents. This skill shortage is partly alleviated by the return of experienced Asians from overseas. For the region to realize its potential, steps need to be taken to train and develop drug development professionals at the industry, regulatory and investigational site levels.

In conclusion, Asia is a key player in the global drug development arena and it will play an increasingly important role in the development of innovative medicines leading to early access to medicines on a global basis.



BIBLIOGRAPHY

Dr. Edmund Tsuei received his undergraduate degree in the United States of America and his doctorate from the University of Sydney in 1980.

Based in Sydney, Australia, Ed has been working in the area of global drug development, conducting high quality clinical trials in the Asia–Pacific region since the mid 1980s. He has built up regional global drug development departments in Asia–Pacific first for Parke–Davis, then for Searle before joining Roche. He is currently Regional Head of Pharma Development Operations, Asia–Pacific–Africa at Roche Products Pty Limited, responsible for global drug development activities in the region. He is a frequent speaker in international conferences on drug development in Asia.

In addition to global drug development, Ed's personal research interest is in the areas of both theoretical and clinical pharmacokinetics and has published many papers in these areas.

CLINICAL TRIAL MAGNIFIER SPEAKER

Andrei KRAVCHENKO, MD, PhD

Kiev-Ukraine

Nov 14, 15:00 – 15:30

Why Clinical Trials in Eastern Europe?

ABSTRACT

Central and Eastern Europe represents one of the regions with clinical trials markets emerging during last decade. The most prominent characteristics of Eastern Europe in regards to clinical trials are its high recruitment rates and high data quality.

The background for this is underlined by the large population at the region, structured and centralized healthcare systems (e.g. in Ukraine and Russia), highly qualified and experienced investigators and site staff members. In addition, the regulatory environment in countries of Eastern Europe makes study authorization process transparent and quick in comparison with countries which clinical trials markets were established earlier.

During the last decade, study budgets for clinical trials ran in Eastern Europe were noticeably lower in comparison with the budgets in other regions with established clinical trials markets. Such cost optimization was achieved by lowering the overall duration of clinical trials. Another factor in lowering the budgets of clinical trials in Eastern Europe was to use local vendors (e.g. local couriers, regional laboratories).

The fact that the majority of clinical trial professionals in Eastern Europe are medically qualified makes cooperation between study sites and CRO's or Sponsor's staff more streamlined and thus, data are clarified during monitoring, minimizing time for data query resolution at the end of the trial.

As confirmation of the Eastern European market's attractiveness, the number of CROs operating in Eastern Europe rose significantly during the last few years. Thus, selection of reliable partner(s) in the Eastern European region became an important task which upon appropriate completion, leads to reaching of goals and exceeding the Sponsor's expectations.



BIBLIOGRAPHY

Dr. Kravchenko holds a PhD in Medicine where his main focus is in the area fungal diseases (tinea pedis and onychomycosis) in patients with diabetes mellitus. His educational background in medicine also includes the areas of Dermatology and sexually transmitted diseases, including HIV.

He stepped into the pharmaceutical world, working as a CRA at Deutsche Homöopathie-Union's representative office in Ukraine, Kiev in 2002. There, he worked in the fields of gynaecology and respiratory tract diseases. In 2003, he took the position of Clinical Trial Manager with responsibilities of local Project Management (mainly projects in respiratory tract diseases and Dementia) and CRA Line Management.

In 2005, he joined Health Research Services Ltd. as Clinical Trial Manager with responsibilities of local Project Management (perimenopausal complaints, respiratory tract diseases, Infectious diseases, gastroenterology, pediatrics) and CRA Line Management, where worked until January 2008.

Shortly after leaving Health Research Services Ltd., he took the role of Head of Representative at the office of Harrison Clinical Research Deutschland GmbH in Ukraine where he is responsible for clinical operations control, line management, management of the office and client contacts.

CLINICAL TRIAL MAGNIFIER SPEAKER

Jerome B ZELDIs, MD, PhD

New Jersey–United States

Nov 14, 15:30 – 16:00

How Does a Bio–Pharma go Global?

ABSTRACT

With US FDA THALOMID® (thalidomide) approval for the treatment of erythema nodosum leprosum, Celgene Corporation considered whether to seek marketing approval outside the United States or wait until its more immature development compounds were ready for marketing authorizations. A decision was made to wait.

While lenalidomide was being developed, it became apparent that this drug had meaningful activity in a variety of neoplastic conditions. As its development proceeded, Celgene began to discuss with multi-national and regional companies about the potential for licensing the drug for distribution outside of the US. Simultaneously, Celgene discussed with Competent Regulatory Authorities about lenalidomide's development programs and determined the types of trials and levels of evidence needed to obtain a license to market the drug. Furthermore Celgene was increasingly conducting its regulatory trials outside of the US and was becoming familiar with investigators, medical institutions, CROs, advocacy groups, and Competent Authorities in Europe, Asia, and Australia. Business development, marketing and others on the commercial side of the business projected the costs and profits to be made by either partnering with another commercial organizations or "going it alone" globally.



BIBLIOGRAPHY

Jerome B Zeldis is CEO of Celgene Global Health and Chief Medical Officer of Celgene Corporation, Summit, New Jersey. Prior to that he was Celgene's Senior Vice President of Clinical Research and Medical Affairs.

He attended Brown University for an AB, MS, followed by Yale University for an MPhil, MD and PhD in Molecular Biophysics and Biochemistry (immunochemistry). Dr. Zeldis trained in Internal Medicine at the UCLA Center for the Health Sciences and Gastroenterology at the Massachusetts General Hospital and Harvard Medical School.

He was Assistant Professor of Medicine at the Harvard Medical School, Associate Professor of Medicine at University of California, Davis, Clinical Associate Professor of Medicine at Cornell Medical School and Professor of Clinical Medicine at the Robert Wood Johnson Medical School in New Brunswick, New Jersey.

Prior to working at Celgene, Dr. Zeldis worked at Sandoz Research Institute and Janssen Research Institute in both clinical research and medical development.

He has been a board member of a few start-up biotechnology companies and is currently on the board of the Semorex Corporation, NJ Chapter of the Arthritis Foundation and the Castleman's Disease Organization.

He has published 105 peer reviewed articles and 24 reviews, book chapters, and editorials.

CLINICAL TRIAL MAGNIFIER CHAIR

SESSION: MAGNIFIER CENSUS POLLING

Chairpersons: Nov 14, 16:30 – 18:00

Johan PE KARLBERG, MD, PhD, BSc

Tzy-Jyun YAO, PhD, MSc, BSc

Johan PE KARLBERG, MD, PhD, BSc
Hong Kong-China



Tzy-Jyun YAO, PhD, MSc, BSc
Hong Kong-China



Professor Johan PE Karlberg has, since its establishment in 1998, been the Director of the Clinical Trials Centre (CTC), The University of Hong Kong. He has a B.Sc. in Statistics and Education (Goteborg, Sweden), a M.D. (Goteborg), and a Ph.D. in Anatomy and Cell Biology (Goteborg). He joined the Department of Paediatrics, The University of Hong Kong in 1993. Dr. Karlberg's research interests cover paediatric endocrinology, biostatistics, and clinical trials; he has his name on 200+ publications and has been involved in supervising some 75 postgraduate students. The main focus of his current activities in the CTC is promotion of Good Clinical Practice (GCP) in the Faculty, in Hong Kong and in the region. Over the past years, CTC has established a large range of trial related services such as central laboratory services, research pharmacy services, project management, monitoring, IRB submission assistance, protocol development, data management and medical statistics. CTC has been, or is currently involved around 500 industry sponsored global clinical trials. In 2008, Dr. Karlberg established a monthly free electronic newsletter on the globalization trends of clinical trials (www.ClinicalTrialMagnifier.com) current with over 12,000 subscribers representing 144 countries.

Dr. T J Yao is an experienced biostatistician. After receiving her PhD in Statistics from the University of Wisconsin at Madison in 1991, she worked in the Department of Epidemiology and Biostatistics of Memorial Sloan-Kettering Cancer Center in New York, the Division of Biostatistics and Bioinformatics of National Health Research Institutes in Taipei, and finally joined the Li Ka Shing Faculty of Medicine of the University of Hong Kong in 2006.

Over the years, Dr. Yao has cumulated extensive experience in collaboration with investigators from the academics, research institutes and the industry. Her experience includes grant applications, protocol development, statistical analysis and manuscript/report writing; research in statistical methodology; and teaching and supervision of postgraduate students. She is particularly interested in the design and analysis of clinical trials. She has numerous publications in international peer-reviewed statistical and medical journals.

During this session we will ask conference participants – using real time electronic polling devices – to reflect on the results of past *Clinical Trial Magnifier* Subscribers' Surveys. These have been conducted into: *Study Site Location Selection Criteria*; *Investigator-Initiated Clinical Studies*; *Phase I Trial Safety Concerns*; *Institutional Indirect Fees and Administrative Fees for Industry Sponsored Clinical Trials*; *Incentives for Participation in Industry Sponsored Clinical Trials*; and *Clinical Research Guidelines*. Other controversial topics identified during the course of the conference will also be subject to polling, with a few delegates invited to reflect on the results obtained.

SUPPORTING ORGANIZATION

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The Hub of Global Clinical Trials



Regional Clinical
Trial Centers



Clinical Trials
Training Academy



Clinical Trials
Technology Development



Public Relations
Worldwide



Collaboration
with the Globe

Korea National Enterprise for Clinical Trials

KoNECT has established in December 2007 with all-out support from the Korean government to meet the increasing demand for clinical trials and to strengthen national capability by fostering the necessary human resources, core technology, and infrastructure to become a global clinical trial hub.

Since the establishment, KoNECT has successfully selected 5 new Regional Clinical Trial Centers(RCTC) and now supports 14 RCTCs all together across Korea. Clinical Trials Training Academy of KoNECT is now running 19 training programs for clinical trial specialists by selecting high quality institutions. KoNECT began its support for clinical trial technology development programs which have been up and running since May 2008. All these are to maximize the impact of concerted support by KoNECT and to create the synergy among the infrastructures, human resources and technology development in clinical trials advancement.

KoNECT has the vision to prepare foundations of a strong, advanced medical industry by implementing advanced clinical trial infrastructures throughout Korea to serve as an international hub for clinical trials and to strengthen the Korean pharmaceutical industry.

CLINICAL TRIAL MAGNIFIER CHAIR

SESSION: BUDGETS - REALISTIC

Chairpersons: Nov 15, 09:00 – 11:00

Alan PAAU, CLP, MBA, PhD

Teck-Onn LIM, MD

Alan PAAU, CLP, MBA, PhD

New York–United States



Teck-Onn LIM, MD

Kuala Lumpur–Malaysia



Vice Provost PaaU is responsible for the strategic management of all technologies and intellectual property that arise from the research activities at Cornell University that includes the Weill Cornell Medical College in New York City, the New York State Agricultural Experiment Station in Geneva, NY, and the parent campus in Ithaca, NY. He also serves as the executive director of the Cornell Center for Technology Enterprise & Commercialization.

As a technology development and management veteran both in industry and in academic, Dr. PaaU is a Certified Licensing Professional™ who holds a PhD degree in Biological Sciences, a Master of Business Administration degree, and attended the Drake University School of Law. Dr. PaaU has supervised the execution of over a thousand technology commercialization agreements and the formation of over 100 new businesses using licensed technologies. His many accolades include the San Diego Bio–Pharma Award, the SDCA Vision Award, listing in the San Diego Union–Tribune “People to Watch” and in the T–Sector Magazine “Power List”, and the UCSD Community Champion Award. Previously, he also received a NATO/EMBO Molecular Biology Fellowship Award and a Sigma–Xi Fellowship Award.

Dr. PaaU currently serves on the board of directors of Vivo Development Ltd., Stilbene Therapeutics Corporation, Horizon Stemtech Corporation, Reparo Therapy, Inc., Raywu Agritech, Inc., InFlora, Inc., the Cornell Research Foundation, Inc., the NanoTecNexus, the BayHelix Group, and Vitis Biosciences, Inc.

Dr. Lim Teck Onn is the Director of Clinical Research Centre, Ministry of Health, Malaysia, a Consultant Nephrologist at the Department of Nephrology Kuala Lumpur Hospital, and an Adjunct Professor at International Medical University. He obtained his MRCP, UK in 1988 and FRCP, Edinburgh in 2000. Apart from his medical qualifications, Dr. Lim also has a Master in Medical Statistics degree from the University of Newcastle, Australia. Throughout his career he has been actively involved in clinical research.

He has more than 50 research publications, mostly in reputable international journals. His paper entitled “Assessing Doctors’ performance: Application of CUSUM technique in monitoring doctor’s performance. International Journal of Quality in Health Care 2002; 14:251–8” was nominated as best paper published for the Peter Reizenstein Prize, a first for Malaysia in association with the journal.

Dr. Lim has been WHO Consultant for GCP in Clinical Trial (2002– 2003) to China (TCM Research Institute Beijing), consultant on Clinical Research and GCP to the Aga Khan University (2005 and 2006), University Medical Centre HCM & MOH Vietnam (2007, 2008), Ministry of Health Brunei (2007, 2008), King Saud University College of Medicine Saudi Arabia (2009).

He is an editor of the journal “Nephrology”, and sits on the Editorial Advisory Board of the journal “Monitor”.

CLINICAL TRIAL MAGNIFIER SPEAKER

Ole M BECH, MD, PhD

Beijing–China

Nov 15, 09:00 – 09:30

Introduction to Clinical Trial Budgets

ABSTRACT

A pivotal factor for a successful collaboration between an investigational site and a Sponsor of a clinical trial is setting up financial terms of the collaboration that adequately and fairly compensate the site for the procedures and time required as per the study protocol. This may on the surface sound easy; yet, experience shows that failure to accurately assess and document the trial related cost before PPV is a common cause of prolonged discussion during trial conduct leading to de-motivation and delays in recruitment.

This paper examines both the basic components of cost at a trial site before, during and after a clinical trial as well as some of the dilemmas both sponsor and investigators have to manage during budget preparation.

Budget for a clinical trial is often broken into following categories: 1) Facilities and administrative cost; 2) Institutional Review Board fee; 3) Investigational drug service; 4) Study specific examinations or tests e.g. ECG, X-rays, laboratory; 5) Cost associated with specific recruitment efforts; 6) Subject cost (travel/parking); 7) Time (investigator and study coordinators); 8) Auxiliary cost (pager/phone/copying) and 9) Record retention fees.

Depending on a trial site's objectives for participation in a given trial different points of contention may arise between the various stakeholders within any of the above cost categories. Mutual understanding and respecting all stakeholders' interests is the key to successful closure of the budget negotiation.

The paper will also review a clinical trial sponsors "system" to assess global trial budgets across a multinational clinical trial.



BIBLIOGRAPHY

Dr. Mølskov Bech graduated from Medical Faculty, University of Copenhagen, Denmark in 1985. From 1985–1987 he held a position as Research Fellow at the Department of Pharmacology, University of Aarhus, with special focus on Clinical Pharmacology and a laboratory model of congestive heart failure. After postgraduate training at Hvidovre and Gentofte County Hospital (1987–1990), he joined Novo Nordisk in 1990 as Project Manager for a development project (LMW Heparin).

In 2002, Dr. Mølskov Bech obtained his MBA from Scandinavian International Management Institute, Copenhagen.

Dr. Mølskov Bech has been working in Asia since 2002, when he was appointed Medical Director, Novo Nordisk Asia Pacific. Since November 2003, Dr. Mølskov Bech has been responsible for the clinical development activities for Novo Nordisk in Asia Pacific, Latin America, Africa and Middle East, East and Central Europe, Australia and New Zealand. During this period the number of patients in clinical trials in the region has more than tripled to around 6000 patients per year.

Dr. Mølskov Bech is a member of Novo Nordisk Global Development Management Team.

CLINICAL TRIAL MAGNIFIER SPEAKER

Henry YAU, MBA, BSc

Hong Kong-China

Nov 15, 09:30 – 10:00

Study Site Budget Development

ABSTRACT

In Asia, a large majority of study sites are located in not-for-profit organizations such as public hospitals and medical universities. Such organizations are not dedicated to conducting clinical studies and normally do not have a financial system tailored to the specific needs of clinical studies. A well-structured study site budget could ensure that study sites have sufficient resources required for conducting a clinical study, and at the same time help streamline the financial management process of study sites, contributing to the successful completion of a clinical study in a high-quality and efficient manner.

Budgets for different clinical studies are different owing to the different protocol requirements, whether on investigational procedures, laboratory tests, drug management procedures, imaging assessments or otherwise. Budgets for different study sites for the same clinical study may also vary greatly because of the differences in study sites' infrastructure, research settings, manpower, experience and administration requirements.

It is important to note that some cost items are fixed in nature (i.e. fixed costs) whilst some others may be linked with the number of subjects screened/enrolled, number of study visits completed, or the period of a study (i.e. variable costs). Costs may either be incurred directly for performance of a clinical study (i.e. direct costs) or allocated/apportioned to a study indirectly (i.e. indirect costs).

The negotiation of a study site budget is not simply bargaining on a budget amount. In many circumstances, the key concern is the budget structure rather than the financial sum. Each study site should carefully consider its specific situation and work out a study site budget both meeting its needs and fitting the sponsor's expectations in terms of budget structure and monetary amount.



BIBLIOGRAPHY

Henry Yau obtained a BSc degree in Biochemistry and an MBA in Finance. He started his career in the pharmaceutical industry since 1993 from a regulatory and marketing position in Rhone-Poulenc, the then largest French pharmaceutical group. Since 2000, Henry has joined the Clinical Trials Centre of The University of Hong Kong and is currently the centre's Assistant Director and Chief Business Officer. Henry is now mainly responsible for directing the business and project coordination functions of the centre, including research ethics affairs, project finance and budget management, contract management, feasibility assessment, proposal development, business infrastructure and services development, formulation and management of strategic alliances, international marketing, and business risk management for clinical trials. Over the years, he has established good collaborative relationships with some 100 major pharmaceutical, medical device and healthcare companies worldwide in some 500 clinical studies.

CLINICAL TRIAL MAGNIFIER SPEAKER

Frank FAN, MD, MBA

Hong Kong-China

Nov 15, 10:00 – 10:30

Negotiating Clinical Trial Budgets

ABSTRACT

Clinical trials budgets are inherently complex. The key components of clinical trials budgets are direct costs and indirect costs.

The budgeting process include the following key steps: evaluating the study protocol, studying feasibility analysis, defining recruitment strategy, converting study plan to cost estimate, submitting and negotiating of the budget and finalizing the budget, and signing the study contract.

The potential fiscal issues of disagreement requiring negotiations between investigators and sponsors are as follows: start up payment covering pre-study activities; patient enrollment fees especially for screen failure; fees for patients drop-out/ lost follow-up, fees for treating patients with adverse events; milestone-based payment schedule; inflation adjustment and contingency funding.

The negotiation between investigators and sponsors should be based on the following principles: learning about the other side's people, culture, their assumptions and how they frame the issue; gathering external standards and criteria; identifying your best alternative to a negotiated agreement (BANTA); preparing for flexibility in the negotiation process, aiming for a win-win solution – consider what a good outcome would be for you and the other side.



BIBLIOGRAPHY

Dr. Fan is the Medical Director of Wyeth Hong Kong Limited.

Dr. Fan holds a Medical Degree from Capital University of Medical Sciences, Beijing, China. He practiced orthopedics and rheumatology for six years prior to joining the pharmaceutical industry in 1994.

Dr. Fan has conducted clinical research in the therapeutic areas of inflammation/immunology, infectious diseases, diabetes, gastroenterology and oncology. He successively held the leadership positions of clinical research and medical affairs in the global pharmaceutical companies in the past 10 years.

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CLINICAL TRIAL MAGNIFIER SPEAKER

Tatyana BENISHEVA, MD, PhD

Sofia–Bulgaria

Nov 15, 10:30 – 11:00

Institutional Indirect and Administrative Fee

ABSTRACT

All 27 Member States (MSs) follow Directive 2001/20/EEC, whereas, a sponsor may not start a clinical trial prior to Ethics Committee issuing a favourable opinion and the Concerned Member State competent authority not informing the sponsor of any grounds for non-acceptance.

The European Clinical Trial Directive does not provide any fee terminology and in Article 6 (j) it is pointed out that the Ethics Committee shall give opinion before a clinical trial commences – on the amounts payable and, where appropriate, the arrangements for rewarding or compensating investigators and trial subjects and the relevant aspects of any agreement between sponsor and site. Obviously, that amount covers the administrative fees, including contract management, budget calculation, and subject compensation.

Additionally, the competent authorities in the EU MSs charge variable administrative fees for preceding scientific and administrative evaluation of the trial, and the authorities of Bulgaria, Estonia, Germany, Ireland, Poland, Portugal, and the UK charge different fees for Phases I, II and III. Conversely, Austria, Belgium, Denmark, Hungary, Latvia, Lithuania, Romania, and Slovakia require a single fee for each phase. Subject to fee in Austria Germany, Ireland, Malta, Poland and Portugal is also Phase IV, between 269 and 3000 Euro.

Ethics Committee fees differ in individual MSs, e.g. Finland, France, Greece, Hungary, Netherland, and the UK have no fees – obviously a motivation for sponsors. In France and the Netherlands, the authorities do not require fees. The European pharmaceutical legislation provide no clarifications or limits of indirect cost as a part of a trial, where normally hospital premises, investigator visits, hospital supporting staff, facilities, etc. are covered, so budget is not fixed.



BIBLIOGRAPHY

Dr. Tatyana Benisheva–Dimitrova is an Associate Professor in Drug Regulatory Affairs at the Faculty of Public Health at the Medical University, Sofia, Bulgaria.

Being the former Director of the Drug Policy Department at the Ministry of Health in Bulgaria, she was directly responsible for establishing Bulgarian pharmaceutical legislation through the period 2000 – 2005. She continues to shape this legislation thanks to her long tenure as a scientific expert at the Bulgarian Drug Agency from 1986 to 1997 pharmaceutical adviser to the Parliamentary Health Commission from 1997 to 2000 and her knowledge as evident from numerous publications.

She was granted an EU–CADREAC scholarship by the German Association for Drug Regulatory Affairs (DGRA) and awarded an MD in Drug Regulatory Affairs (2004/2005) at the Bonn University, Germany. Her considerable experience in pharmaceutical authorization procedures acquired over a long experience are currently being utilized in many projects on consultant basis in the drug regulatory affairs at EU level (Centralized, MRP and DP) and clinical trial conducting as well.

Since 2005 she is consultant of Bulgaria of the single world wide data base of Thomson Reuters (www.idrac.com), of the marketing authorization requirements and as well the legal base of clinical trials in the country.

CLINICAL TRIAL MAGNIFIER CHAIR

SESSION: AGREEMENTS - OUTLINE

Chairpersons: Nov 15, 11:30 – 13:00

Chaya MAZOUZ, BSc, RN, MA

Henry YAU, MBA, BSc

Chaya MAZOUZ, BSc, RN, MA
Haifa-Israel



Henry YAU, MBA, BSc
Hong Kong-China



Chaya Mazouz currently holds the position of VP Clinical and Regulatory Affairs for Pluristem Ltd., a bio-therapeutics company dedicated to the commercialization of allogeneic cell therapy products, derived from human placenta. Chaya is a certified nurse with a BSc and MA from the Hebrew University of Jerusalem. Prior to joining Pluristem, Chaya held the position of Clinical Operations Director for Medgenics, a clinical-stage biopharmaceutical company involving gene therapy, where she engineered Phase I/II clinical studies. Previously, Ms. Mazouz served as Clinical Manager for TransPharma Medical, a drug delivery company, where she was responsible for managing all of the company's clinical activities. In previous positions, Ms. Mazouz led a multi-center phase II study for Pharmos, a pharmaceutical company, and was CRA and Project Manager at IDgene, a startup company engaged in gene discovery.

Henry Yau obtained a BSc degree in Biochemistry and an MBA in Finance. He started his career in the pharmaceutical industry since 1993 from a regulatory and marketing position in Rhone-Poulenc, the then largest French pharmaceutical group. Since 2000, Henry has joined the Clinical Trials Centre of The University of Hong Kong and is currently the centre's Assistant Director and Chief Business Officer. Henry is now mainly responsible for directing the business and project coordination functions of the centre, including research ethics affairs, project finance and budget management, contract management, feasibility assessment, proposal development, business infrastructure and services development, formulation and management of strategic alliances, international marketing, and business risk management for clinical trials. Over the years, he has established good collaborative relationships with some 100 major pharmaceutical, medical device and healthcare companies worldwide in some 500 clinical studies.

CLINICAL TRIAL MAGNIFIER SPEAKER

Audrey SHUM, LLB (HKU), LLM (Cantab)

Hong Kong-China

Nov 15, 11:30 – 12:00

Development of Clinical Trial Agreements

ABSTRACT

In this session, the speaker will share some practical tips with the audience on how to develop clinical trial agreements. The key areas to be covered include: choice of the Sponsor's template or the study centre/hospital's template; how understanding of the regulatory environment and practices of the local study centres/hospitals may help sponsors and study centre better prepare in developing an appropriate clinical trial agreement; a brief introduction of the types of clinical trial agreements; and discussion of the key provisions to be incorporated into a clinical trial agreement and the issues to look out for when drafting such provisions.



BIBLIOGRAPHY

Audrey is a Consultant in Clifford Chance's Intellectual Property Group in Hong Kong. She specializes in both contentious and commercial IP matters. She has extensive experience in advising on the exploitation of IPRs in Hong Kong and China and in advising on the strategies and supervising the conduct of intellectual property litigations in Hong Kong and China.

Audrey's recent experience in the pharmaceutical and healthcare industry includes advising a leading pharmaceutical company on the regulatory and IP issues arising out of a merger of two pharmaceutical companies, advising on a nutrition product manufacturer on its concern over a Consumer Council Report, reviewing and advising on issues relating to and revising clinical trial agreements for pharmaceutical companies and advising an international pharmaceutical company on its patent issues.

Audrey is currently supervising the conduct of one of the largest copyright infringement actions in China, a complex trade mark and unfair competition litigation against a notorious trade mark infringer, the appeals to the 1st instance judgment of a trademark infringement action and a copyright infringement action; and advising the world leading airplane manufacturer, supermarket chain, luxury car manufacturer, pharmaceutical manufacturer, online game providers and financial institutions on trade mark, copyright, design or patent and other IP related issues in commercial transactions, technology license and transfer agreements, clinical trial agreements, compliance programs and litigation and administrative cases in China and Hong Kong.

CLINICAL TRIAL MAGNIFIER SPEAKER

Rodney GALE, BSc, DPhil, MBA

London-United Kingdom

Nov 15, 12:00 – 12:30

Negotiating Clinical Trial Agreements

ABSTRACT

This presentation is a very practical review of the art of negotiating and agreeing the terms for conducting a clinical trial, from the viewpoint of a very experienced provider of research services in the UK. It is not easy to understand the true cost of a trial and it can be an even more difficult process to arrive at the price at which all parties are willing to proceed; market forces play a part. The majority of contract negotiation is around the price and the presentation of the financial information. Intellectual property and publication rights are points of common contention and the responsibility for care of a patient who reacts adversely to a novel treatment is often debated. Much of the remaining contract is filled with provisions for things that may go wrong, but rarely do, and detain only those with a legal interest.

The author will share his experience of getting the best out of contract negotiations and will illustrate the challenges of negotiation with many examples. The art is one of estimating the risks to your organization and balancing the time and effort to moderate those risks against the likely gains. There are no ready answers but there are many choices some of which are described in the paper.



BIBLIOGRAPHY

Rodney Gale has worked in contract research for over 35 years, in a variety of industries, and has a wealth of experience in estimating, pricing, negotiating and managing commercial contracts. He has a BSc and a DPhil in Physical Chemistry and an MBA from London Business School. For the past 10 years, he was the Director of Research Support at the Hammersmith Hospital, one of the most research active centres in the United Kingdom. He was responsible for research governance and managed a portfolio of biomedical research worth £100million per annum. He ran a commercial contract research unit that had an annual turnover of £2million and handled over 100 separate contracts in a wide range of specialties and with a large number of biomedical companies and contract research organizations.

Since May 2009, he has been continuing his work in biomedical research as a freelance management consultant. He runs in-house coaching and training in all aspects of trial management.

CLINICAL TRIAL MAGNIFIER SPEAKER

Alan PAAU, CLP, MBA, PhD

New York–United States

Nov 15, 12:30 – 13:00

Principles of Investigator Initiated Trial Agreements

ABSTRACT

Academic medical centers and research institutes are rich sources for potentially useful new therapeutics, new therapy approaches, and new uses of existing therapeutics. Academic researchers are generally driven by knowledge and curiosity and are quite different from industry that are logically more driven by products and profit. While this difference can set a stage for a meaningful collaborative relationship, it also may create tension due to the cultural difference that may precipitate to conflict and failure to collaborate. In general, Investigator Initiated Trials face a slightly different set of institutional policy and regulation hurdles and this session will try to address the principles behind them and possible approaches to address them to mutual satisfaction.



BIBLIOGRAPHY

Vice Provost Paa is responsible for the strategic management of all technologies and intellectual property that arise from the research activities at Cornell University that includes the Weill Cornell Medical College in New York City, the New York State Agricultural Experiment Station in Geneva, NY, and the parent campus in Ithaca, NY. He also serves as the executive director of the Cornell Center for Technology Enterprise & Commercialization.

As a technology development and management veteran both in industry and in academic, Dr. Paa is a Certified Licensing Professional™ who holds a PhD degree in Biological Sciences, a Master of Business Administration degree, and attended the Drake University School of Law. Dr. Paa has supervised the execution of over a thousand technology commercialization agreements and the formation of over 100 new businesses using licensed technologies. His many accolades include the San Diego Bio-Pharma Award, the SDCA Vision Award, listing in the San Diego Union-Tribune "People to Watch" and in the T-Sector Magazine "Power List", and the UCSD Community Champion Award. Previously, he also received a NATO/EMBO Molecular Biology Fellowship Award and a Sigma-Xi Fellowship Award.

Dr. Paa currently serves on the board of directors of Vivo Development Ltd., Stilbene Therapeutics Corporation, Horizon Stemtech Corporation, Reparo Therapy, Inc., Raywu Agritech, Inc., InFlora, Inc., the Cornell Research Foundation, Inc., the NanoTecNexus, the BayHelix Group, and Vitis Biosciences, Inc.

CLINICAL TRIAL MAGNIFIER CHAIR

SESSION: OPERATION – EFFICIENCY

Chairpersons: Nov 15, 14:00 – 16:00

Yil-Seob LEE, MD, PhD

Tatyana BENISHEVA, MD, PhD

Yil-Seob LEE, MD, PhD

Seoul–South Korea



Tatyana BENISHEVA, MD, PhD

Sofia–Bulgaria



Yil-Seob Lee is currently working for GlaxoSmithKline (GSK) Korea, holding the title of Director of Medical & Regulatory. He is also working as a director of KSCPT (Korean Society of Clinical Pharmacology and Therapeutics), and is an affiliated professor in Yonsei University in Seoul, Korea.

Before joining GSK, he held the positions of Medical Director of Aventis Pharma Korea and Handok Pharmaceuticals Co. from 1990 to 2004.

He graduated from Yonsei University College of Medicine in Seoul, Korea in 1983 and had residence training in Pediatrics at Yonsei University Hospital. He also took up fellowship training in Clinical Pharmacology at Cornell University in New York. He received his PHD in Pharmacology from Korea University in Seoul, Korea, and his MBA from Yonsei University.

Dr. Tatyana Benisheva-Dimitrova is an Associate Professor in Drug Regulatory Affairs at the Faculty of Public Health at the Medical University, Sofia, Bulgaria.

Being the former Director of the Drug Policy Department at the Ministry of Health in Bulgaria, she was directly responsible for establishing Bulgarian pharmaceutical legislation through the period 2000 – 2005. She continues to shape this legislation thanks to her long tenure as a scientific expert at the Bulgarian Drug Agency from 1986 to 1997 pharmaceutical adviser to the Parliamentary Health Commission from 1997 to 2000 and her knowledge as evident from numerous publications.

She was granted an EU-CADREAC scholarship by the German Association for Drug Regulatory Affairs (DGRA) and awarded an MD in Drug Regulatory Affairs (2004/2005) at the Bonn University, Germany. Her considerable experience in pharmaceutical authorization procedures acquired over a long experience are currently being utilized in many projects on consultant basis in the drug regulatory affairs at EU level (Centralized, MRP and DP) and clinical trial conducting as well.

Since 2005 she is consultant of Bulgaria of the single world wide data base of Thomson Reuters (www.idrac.com), of the marketing authorization requirements and as well the legal base of clinical trials in the country.

CLINICAL TRIAL MAGNIFIER SPEAKER

Yuet-Meng CHEONG, MBBS, MSc, FRCPath

Selangor-Malaysia

Nov 15, 14:00 – 14:30

Clinical Research Centre Infrastructure Development

ABSTRACT

This presentation will focus on the infrastructure development for a Clinical Research Centre (CRC) to support Phase II to IV Clinical Trials in a private hospital. Setting up a CRC in a private hospital has some unique challenges not seen in a public hospital or institution. A questionnaire was first sent to all the doctors to find out their interest in conducting clinical trials and the support they would require. Most doctors were not interested and cited time constraints to be the main reason for not participating in clinical trials. However there was a handful who were keen and at least one of them was already actively conducting industry sponsored clinical trials. The main support required was administrative and logistics matters like contract negotiation and Ethics and Clinical Trial Import license application.

The infrastructure development can be divided into the physical and the non-physical requirements. The physical ones are suitable and adequate space allocation for offices, consultation, monitoring activities, documents, investigational product storage, a small laboratory and a conducive and private area for trial patients. Next to consider are the basic standard office and clinic equipment, temperature-control refrigerators for drugs and lab samples, freezers, centrifuge and good broadband facilities. However the major challenges lie in the non-physical requirements like human resources, funding, organizational infrastructure development in legal and financial support, work flow, SOPs, increasing awareness and education of both doctors and clinical support staff and the setting up of a GCP compliant Independent Ethics Board. Another challenge is the decision on the size and capacity of the centre. We decided to start small and allow for expansion as the demand increases.

Hence with a one-stop centre to support clinical trials, we hope more doctors will participate and more sponsors will place their clinical trials in our hospital and be assured that GCP compliant trials are possible in a private hospital.



BIBLIOGRAPHY

Presently Dr. Cheong is the Associate Professor of Medical Microbiology and Clinical Investigation Unit of Monash University Sunway Campus, Malaysia. She is also the Clinical Director of the Clinical Research Centre at Sunway Medical Centre, a private hospital in Kuala Lumpur. She obtained her medical degree from the University of Malaya and later her Masters in Medical Microbiology from the London School of Hygiene and Tropical Medicine followed by the Membership/Fellowship of the Royal College of Pathologists (UK).

She started her career with the Malaysian Ministry of Health at the Institute of Medical Research and worked there for 16 years. Her main areas of research were in Clinical Microbiology and Antibiotic Resistance. She was also involved in the planning, execution and delivery of the teaching program of the Institute which included basic and advanced programs for Medical Laboratory Technologists, post graduate training for doctors in Pathology & Medical Microbiology as well as being initially a module coordinator and subsequently Dean of the IMR Postgraduate Diploma in Medical Microbiology that was held annually under the aegis of the South East Asia Ministers' of Education & Tropical Medicine Program.

Subsequently she joined Pfizer as the Medical Director of Pfizer Malaysia/Singapore/Brunei to become the Regional Director of Clinical Operations for Asia. During her 13 years in the industry she has developed and introduced a number of Clinical Trials to Asia and is well versed in the operational, regulatory and ethical aspects of conducting clinical trials in this region.

CLINICAL TRIAL MAGNIFIER SPEAKER

Jade LIU, MSc

Taipei-Taiwan

Nov 15, 14:30 – 15:00

Site Management Efficiency

ABSTRACT

Pending



BIBLIOGRAPHY

Jade Liu is the Chief Operation Officer in Taiwan Total Management Consulting Ltd (TTMC), the first and largest site management organization company in Taiwan. With 6 contracted hospitals across northern, central and southern Taiwan, TTMC provides overall site management services for pharmaceutical and biotech companies when conducting clinical trials in Taiwan.

Jade Liu is very familiar with the medical and biotech environment in Taiwan. With a master's degree in Biochemistry, her previous experiences include: working as a CRO division manager in FBC, RD director in BIONET and orphan drug business manager in Excelsior Group. Prior to joining TTMC, she worked with a CRO – a SMO company, holding the title of Chief Operation Officer.

CLINICAL TRIAL MAGNIFIER SPEAKER

Simon DONELL, BSc, FRCS (Orth), MD

Norwich–United Kingdom

Nov 15, 15:00 – 15:30

Clinical Research in the UK: The Comprehensive Research Networks

ABSTRACT

In 2006 the Department of Health introduced a policy document called “Best Research for Best Health” with the aim of making the UK the ‘the best place in the world for health research, development and education’. This required introducing the necessary infrastructure, commissioning and delivery systems to be put in place. It also recognized that the NHS research funding streams needed re-organizing.

A new over-arching body to run Research throughout the NHS (National Health Service) was created; the National Institute for Health Research (NIHR). The delivery systems are the Clinical Research Networks which facilitate clinical trials, both commercial and non-commercial, as well as other well-designed studies. A number of disease-specific networks e.g. diabetes and cancer already existed, a new primary care network was introduced, and Comprehensive Clinical Research Networks to cover all aspects of medicine and surgery, with national coverage.

This lecture will present the implementation of this policy and how it affects researchers at a local level. It will look at the Norfolk & Suffolk Comprehensive Local Research Network as an example, and focus on the Injuries & Accidents portfolio.

The importance of commercially-sponsored NHS-branded research in the UK will be discussed emphasizing the advantage for the company of an established infrastructure and flexibility to enroll new research sites if recruitment targets are not met.

The NHS through the NIHR is creating a major shift in the way research is conducted in the UK. Considerable resources have been put into this change. The result is that there are new opportunities for clinical research which is targeted for the benefit of the UK patients.



BIBLIOGRAPHY

Simon Donell is a Consultant Orthopaedic surgeon and the lead for research in the Department of Orthopaedics at the Norfolk & Norwich University Hospital and Co-Chairman of the Norwich Musculoskeletal Research Group. He holds an honorary Professorship with the Medical School at the University of East Anglia. He is the Lead for Injuries and Accidents and Co-Lead for Musculoskeletal Disease for the Norfolk & Suffolk Comprehensive Local Research Network. He is Co-Editor of The Knee journal and a Specialist Advisor on the Interventional Procedures Programme for the National Institute for Health & Clinical Excellence (NICE).

His research interests cover the range of musculoskeletal disease in collaboration with other disciplines including; matrix metalloproteinases in articular cartilage and Dupuytren's disease, health technology assessments for the Department of Health on bone morphogenetic protein with the health economists in the School of Medicine UEA, studies on the outcome of various joint replacements funded by industry, commercially sponsored studies on the accelerated healing of fractures, clinical studies on patellar instability including new imaging techniques, and an educational programme to train novice surgeons and other healthcare workers in knee replacement.

CLINICAL TRIAL MAGNIFIER SPEAKER

Louis CHOW, MBBS, MS

Hong Kong-China

Nov 15, 15:30 – 16:00

Investigator Breast Cancer Trial Network in China and Asia

ABSTRACT

Breast cancer incidence in Asia is dramatically increasing in recent years with advances of diagnostic techniques and comprehensive screening programs in some countries. Although numerous breast cancer clinical trials originating from western countries has entered into Asia-Pacific regions, and that more treatment options are now available to regional breast cancer patients, the epidemiology, clinical presentation and possible side effects profiles of breast cancer patients in Asia are not exactly the same as their Western counterparts. The patients are younger and their tumors are larger. They react differently to anthracyclines and taxanes. For these reasons, we need to understand further the differential nature of the disease as well as treatment effects and responses. The development of a trial network in Asia is therefore important to gather solid evidence, particularly for Asia. The development of such network is however challenging. Although there is no shortage of investigators who are experienced and interested in participating in clinical trials, the setting up of the network is not straight forward, as the regulatory process of the participating countries are different, especially when the trial is more on investigational drugs. The length of the approval process also differs with some taking especially long for approving the trial and issuing certification. Despite these challenges, the development of the network is still worthwhile. The data generated could be beneficial to many subsequent patients. The practices and guidelines of management could be modified according to the trial results to be more appropriately suited for Asians. The data generated could also provide a platform to design new trials to further improve on the treatment response and effects. Furthermore, the establishment of a trial network can also share the financial burden of conducting a clinical trial, especially for those clinicians interested in developing their own research projects, but with financial constraints. The network allows redistribution of resources so that more large-scale and high-tech studies could be done within the region.



BIBLIOGRAPHY

Louis WC Chow is a Medical Director of the Comprehensive Centre for Breast Diseases at the UNIMED Medical Institute in Hong Kong, Executive Director of the Organisation for Oncology and Translational Research in Hong Kong, Honorary/Visiting Professor of the Clinical Trials Centre at the University of Hong Kong, the Ningxia Medical College School of Clinical Medicine in Ningxia, China, Tohoku University in Sendai, Japan, Wuhan University of Science and Technology, China and Honorary Consultant of Kiang Wu Hospital in Macao. Professor Chow also holds positions of the Honorary Secretary at the Hong Kong Academy of Medicine, the Steering Committee Member on e-Health Record Sharing of the Food and Health Bureau, the Government of the HKSAR, the Task Group Member on Breast Cancer Management of Hospital Authority in Hong Kong, as well as the immediate past President of the Asian Breast Cancer Society.

Professor Chow received his medical education at the University of Hong Kong. He underwent sabbatical trainings at Memorial Sloan-Kettering Cancer Center in New York, Yale University in New Haven, Connecticut, and the University of Southern California in Los Angeles. Professor Chow returned to the University of Hong Kong as Assistant/Associate Professors at Department of Surgery of the University. Apart from his clinical and teaching duties he also served as an Associate Dean of the Faculty of Medicine, a Deputy Director of Centre of Education and Training at Department of Surgery, and examiners for postgraduate examinations as well as supervisors of doctorate and master degree students.

CONFERENCE ORGANIZER



Clinical Trials Centre The University of Hong Kong

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- *Successfully set up a multi-centre phase 3 trial involving 7 study sites and 7 referral centers in HK from feasibility assessment to study initiation in 5 months

Contact :
Clinical Trials Centre, HKU
Email: ctcentre@hkucc.hku.hk

Ten reasons for conducting clinical trials in Hong Kong:

1. **Excellent infrastructure** - Transportation, work force and legal framework.
2. **English** - One of the official languages. Hospital records are all in English.
3. **Outstanding healthcare system** - Public hospitals provide 90% of the medical care in HK. Medical records are electronic and centrally stored.
4. **Frequent ethics committee review meeting** - Every 2 weeks.
5. **Simple regulatory requirements and quick review process** - Shorten review time to 30 working days in 2010. No regulatory review required for device or cell therapy trials.
6. **Leading clinical research city** - HK is among the leading clinical research cities world-wide.
7. **Scientific leadership in clinical research in Asia** - HK has 2 medical schools with many years of high quality clinical research output. The University of Hong Kong was rated as the leading (No.1) university in Asia (2009).
8. **Conducting global clinical trials** - HK has a long and impressive track record of conducting global clinical trials.
9. **China SFDA accredited centers** - A numbers of study centres possess the accreditation.
10. **Clinical Trials Centre, HKU** - HK has an Asian leading Clinical Trials Centre which makes standardized budgets, contracts and ethics committee applications possible under all the public hospitals.

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CLINICAL TRIAL MAGNIFIER CHAIR

SESSION: OPERATION - EDUCATION

Chairpersons: Nov 15, 16:30 – 18:00

Melody H LIN, PhD

Ling SU, PhD

Melody H LIN, PhD

Rockville–United States



Ling SU, PhD

Shanghai–China



As Deputy Director of the Office for Human Research Protections – OHRP (formerly the Office for Protection from Research Risks – OPRR), Dr. Lin is responsible for the management of OHRP policy, personnel, and budgetary matters regarding biomedical and behavioral research at both the national and international level. Dr. Lin also serves as the Director, Office of International Activities at OHRP. Dr. Melody Lin, a native of Taiwan, received a BS degree in Pharmacy, and is a Registered Pharmacist. She received her PhD in Microbiology/Immunology and conducted research at the George Washington University Medical Center and the National Cancer Institute, National Institutes of Health (NIH). Dr. Lin is a Captain in the US PHS Commissioned Corps. Previous OHRP/OPRR duties include serving as AIDS Coordinator, Chief of the Compliance Oversight Branch, and Director of Division of Human Subject Protections. She frequently is invited, by various organizations, to discuss changing landscapes of human subject protection and compliance oversight in clinical trials and federal perspectives relating to IRB issues. Captain Lin is a member of the Advisory Committee of the National Research Program in Genomic Medicine in Taiwan, is the US liaison to the National Council on Ethics in Human Research in Canada, and is a member of the Advisory Council in European Forum on Good Clinical Practice. Notably, she has organized in excess of one hundred conferences for OHRP/OPRR national workshops and scientific symposia.

Dr. Ling Su is currently Vice President, Clinical Research and Development – Asia Pacific Research Organization in Wyeth, responsible for clinical development and research operations in the Asia Pacific region. He has 20 years of experience in the pharmaceutical industry and the regulatory agency, in both US and Asia, and in a variety of therapeutic or disease areas. He started his career in the 1980s working in the Bureau of Drugs of the Ministry of Health, the Chinese drug regulatory agency. He was a Visiting Scientist in the Center for Drug Evaluation and Research, US FDA, in 1992–1993. He joined Merck Research Laboratories, Merck & Co., in US in 1996 as an Epidemiologist, was the Medical Director for Merck Sharp & Dohme (China) in 2000–2002 and was Senior Director, Global Strategic Regulatory Development in MRL in 2003. Prior to his current position, he was the International Pharma Development Director and subsequently, the Medical and Pharma Development Director at Shanghai Roche –2003–2007. He received his BS degree in Clinical Pharmacology from Shanghai Medical University, China; and MS degree in Clinical Pharmacy and PhD in Epidemiology, both from the University of North Carolina at Chapel Hill, USA. His professional experience and interests encompass the fields of regulatory affairs, clinical research and development, R&D strategies, pharmaco-epidemiology, and outcomes research. He currently serves on the Board of Directors of the Drug Information Association (DIA) and chairs the DIA Advisory Council of China. He is an adjunct professor at the College of Pharmacy, Fudan University in Shanghai, China.

CLINICAL TRIAL MAGNIFIER SPEAKER

Marisa PETERSEN, PhD

Sydney–Australia

Nov 15, 16:30 – 17:00

Educating Study Site Staff on GCP Compliance

ABSTRACT

Educating site staff is critical to the conduct of high quality clinical research. Ethics committees, investigators, study co-ordinators, pharmacy and laboratory staff all need to clearly understand what is required and how to implement the requirements.

This session will take the audience back to the basics of why research is conducted and move through a series of requirements which have been developed to ensure that the outputs from the research are meaningful and are able to be published, patented or translated into clinical practice.

Education is more than “knowing the rules” – although that in itself can be a challenge in clinical research where there is a lack of formal education opportunities. However, it is even more important to consider how knowledge can be translated into practice, the value of practical application and feedback, how opportunities for discussion and debate can be developed, and the importance of staying aware of changing requirements and of further development of skills.

A range of options for gaining training and developing efficient structures for sharing of knowledge will be presented. Feedback will be sought from the audience on what is considered most effective for them. Feedback will also be sought on what are considered the barriers to gaining training and education in clinical research with a view to determining potential solutions.



BIBLIOGRAPHY

Marisa completed her pharmacy degree at the University of Sydney and continued her studies with a PhD in Clinical Pharmacology and Pharmacokinetics. Marisa worked in the pharmaceutical industry from 1989 until 2005, fulfilling roles in Regulatory Affairs, Clinical Research and Project Management. During the last 7 years she led the Australian and Asia-Pacific operations of a global CRO, and developed a network of offices in the Asia-Pacific region.

During this period, Marisa was active in ARCS – working on Education SubCommittees, organising committees for Conferences, and on the Board, with 3 years as President. Marisa took her current role as CEO of ARCS in late 2005, with a focus on developing the role of ARCS as a liaison between the Australian therapeutic goods industry, government and regulators and increasing the training opportunities available to drug development scientists working in the pharmaceutical and allied industries.

ARCS has a strategic commitment to extending the professional development opportunities afforded to Australian ARCS members to all professionals working in therapeutic goods development in the Asia Pacific region. The development of e-learning and Certification programs for industry and research personnel are key to reaching these goals.

CLINICAL TRIAL MAGNIFIER SPEAKER

Johan PE KARLBERG, MD, PhD, BSc

Hong Kong-China

Nov 15, 17:00 – 17:30

Educating IRB Members

ABSTRACT

Several important ethical issues of clinical trials must be correctly addressed for Ethics Committee approval, ranging from risk-benefit ratio, vulnerability of subjects and sensitive privacy concerns, to contents of informed consent, advertising for recruitment of subjects and the Investigator's qualification. A clinical trial that will not advance knowledge about a certain treatment should not be conducted, since the risk-benefit ratio for subjects will be infinitely, unacceptably high. For this reason, IRB review should also consider the scientific value of an IRB application. Reviewing a trial protocol requires discussion of its scientific soundness. To enable an informed, detailed discussion, IRB members must be able to understand the scientific and clinical rationale behind the proposal. In addition, data collected during a clinical trial must be free of errors, since it is intended for use as an important body of evidence when a new medicinal product is reviewed by a governmental regulatory body. An IRB review thus includes the three elements – Ethics, Science and Quality Assurance.

New ethical principles are emerging along with new clinical research regions, increasing demand for proper and continuous training of IRB members. For this purpose, we are currently producing a guideline book entitled "*Reviewing Clinical Trials: A Guide for Ethics Committees*", supported by an unconditional grant from Pfizer Inc., New York, US. The project includes advisors representing WHO, WMA, academia and accreditation institutions from virtually all geographic regions – from North America, South America and Europe to East Europe, Asia and Africa. Our target is to complete the project during the second quarter of 2010.



BIBLIOGRAPHY

Professor Johan PE Karlberg has, since its establishment in 1998, been the Director of the Clinical Trials Centre (CTC), The University of Hong Kong. He has a BSc in Statistics and Education (Goteborg, Sweden), a MD (Goteborg), and a PhD in Anatomy and Cell Biology (Goteborg). He joined the Department of Paediatrics, The University of Hong Kong in 1993. Dr. Karlberg's research interests cover paediatric endocrinology, biostatistics, and clinical trials; he has his name on 200+ publications and has been involved in supervising some 75 postgraduate students. The main focus of his current activities in the CTC is promotion of Good Clinical Practice (GCP) in the Faculty, in Hong Kong and in the region. Over the past years, CTC has established a large range of trial related services such as central laboratory services, research pharmacy services, project management, monitoring, IRB submission assistance, protocol development, data management and medical statistics. CTC has been, or is currently involved around 500 industry sponsored global clinical trials. In 2008, Professor Karlberg established a monthly free electronic newsletter on the globalization trends of clinical trials (www.ClinicalTrialMagnifier.com) current with over 12,000 subscribers representing 144 countries.

CLINICAL TRIAL MAGNIFIER CLOSING

Edmund S TSUEI, BSc, MSc, PhD

Johan PE KARLBERG, MD, PhD, BSc

Nov 15, 17:30 – 17:45

CONFERENCE SUMMARY AND CLOSING



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Magnifier Advisory Board – 103 in number

In November/December 2008 we invited our subscribers to become Advisory Board Members of the *Clinical Trial Magnifier*, to be involved in its further development including improvement of content, contributing articles, advising/speaking on an upcoming conference, and participating in a trial management standardization group.

We have now 103 advisors as listed above from 30 countries/regions with about half representing the industry and the other half academia/other sites in Australia, Belgium, Botswana, Brazil, Canada, China, Denmark, Germany, Hong Kong, Hungary, India, Iran, Israel, Italy, Japan, Korea (South), Malaysia, Mexico, Netherlands, Pakistan, Russia, Singapore, South Africa, Spain, Sweden, Switzerland, Taiwan, Turkey, Ukraine, UK and US.

Several of the advisors have contributed with comments to previous *Magnifier* articles/surveys.

The criteria to become an Advisory Board Member is that you have an interest in clinical trial matters; whether regulatory, ethical, design, medical writing, quality assurance, administration, management or trial conduct. As a member you can contribute as much as you wish and you can leave the Advisory Board at any time.

If you wish to become a *Magnifier* Advisory Board member, please send a message to EditorialBoard@ClinicalTrialMagnifier.com.

New Trial Registrations (Table 1 of 3)

The most recent industry sponsored clinical trials testing drugs, biologicals or medical devices registered with www.ClinicalTrials.gov registered from October 1, 2009 and still not activated (Planning) or recruiting (Recruiting) subjects on October 27, 2009.

Status	Link/ID	Type	Phase	Sponsor	Size (n)	Min age	Max age	Condition
Planning	NCT00996151	Drug	1	Acrux Dds	10	18 Years	70 Years	Hypergonadism
Planning	NCT00997945	Drug	1	AstraZeneca	15	50 Years	N/A	Advanced Solid Malignancies
Planning	NCT00999882	Drug	1	AstraZeneca	80	18 Years	N/A	Advanced Hepatocellular Carcinoma
Planning	NCT01000896	Drug	1	AstraZeneca	27	20 Years	N/A	Epithelial Ovarian Cancer
Planning	NCT01001442	Drug	1	Biotest	80	18 Years	N/A	Multiple Myeloma
Planning	NCT00998296	Drug	1	Boehringer Ingelheim	24	18 Years	N/A	Neoplasms
Planning	NCT00996879	Drug	1	Bristol-Myers Squibb	14	18 Years	49 Years	Hepatitis C
Planning	NCT00996892	Drug	1	Genentech	62	18 Years	N/A	Solid Cancers
Planning	NCT00997919	Drug	1	Genentech	22	18 Years	50 Years	Healthy
Planning	NCT00999128	Drug	1	Genentech	50	18 Years	65 Years	Healthy
Planning	NCT00990054	Drug	1	Genzyme	88	18 Years	70 Years	Acute Myeloid Leukemia
Planning	NCT00991133	Drug	1	Genzyme	12	1 Year	30 Years	Acute Lymphoblastic Leukemia
Planning	NCT00992121	Drug	1	GlaxoSmithKline	12	18 Years	N/A	Renal Cell Carcinoma
Planning	NCT00996268	Drug	1	GlaxoSmithKline	96	18 Years	50 Years	Hypertriglyceridemia
Planning	NCT00996671	Drug	1	GlaxoSmithKline	60	18 Years	65 Years	Cancer
Planning	NCT00996762	Drug	1	GlaxoSmithKline	432	18 Years	75 Years	Solid Tumors
Planning	NCT01000857	Drug	1	GlaxoSmithKline	26	20 Years	64 Years	Healthy Volunteer
Planning	NCT00998283	Drug	1	Hanmi	40	20 Years	45 Years	Healthy
Planning	NCT01001299	Drug	1	Hoffmann-La Roche	20	18 Years	65 Years	Malignant Melanoma
Planning	NCT00991562	Drug	1	Immunogen	60	18 Years	N/A	Multiple Myeloma
Planning	NCT00989300	Drug	1	Janssen	36	18 Years	50 Years	Healthy
Planning	NCT00990808	Drug	1	Merck	40	18 Years	70 Years	Dyslipidemia
Planning	NCT00998985	Drug	1	Merck	36	18 Years	65 Years	Hepatitis C
Planning	NCT00994123	Drug	1	Merrimack	40	18 Years	N/A	Carcinoma, Non-Small-Cell Lung
Planning	NCT00997399	Drug	1	Novartis	28	18 Years	N/A	Advanced Solid Tumors
Planning	NCT00988598	Drug	1	Pfizer	15	55 Years	85 Years	Alzheimer's Disease
Planning	NCT00988949	Drug	1	Pfizer	20	21 Years	55 Years	Bipolar Depression
Planning	NCT00989079	Drug	1	Pfizer	24	18 Years	55 Years	Type 2 Diabetes Mellitus
Planning	NCT00989391	Drug	1	Pfizer	36	21 Years	55 Years	Healthy
Planning	NCT00990613	Drug	1	Pfizer	20	50 Years	85 Years	Huntington's Disease
Planning	NCT00990756	Drug	1	Pfizer	24	21 Years	55 Years	Healthy
Planning	NCT00990990	Drug	1	Pfizer	68	18 Years	55 Years	Tuberculosis
Planning	NCT00991159	Biological	1	Pfizer	48	18 Years	70 Years	Healthy Volunteers
Planning	NCT00992342	Drug	1	Pfizer	36	18 Years	55 Years	Healthy
Planning	NCT00999817	Drug	1	Pfizer	14	18 Years	55 Years	Healthy
Planning	NCT00989521	Drug	1	Pulmatrix	8	18 Years	60 Years	Bronchial Diseases
Planning	NCT01001221	Drug	1	Sanofi-Aventis	30	18 Years	N/A	Neoplasms, Malignant
Planning	NCT00997360	Drug	1	Wyeth	80	18 Years	N/A	Advanced Malignant Solid Tumors
Planning	NCT00990704	Drug	2	Abbott	45	20 Years	N/A	Hemodialysis
Planning	NCT00995345	Drug	2	Activx	400	18 Years	75 Years	Type 2 Diabetes
Planning	NCT00992563	Drug	2	Alcon	42	50 Years	N/A	Wet ARMD
Planning	NCT01001091	Drug	2	Alcon	180	18 Years	N/A	Allergic Conjunctivitis
Planning	NCT00991458	Drug	2	Allergan	591	21 Years	50 Years	Laser In Situ Keratomileusis
Planning	NCT01001195	Drug	2	Allergan	150	18 Years	N/A	Primary Open-Angle Glaucoma
Planning	NCT00989261	Drug	2	Ambit	180	18 Years	85 Years	Acute Myeloid Leukemia
Planning	NCT00991419	Drug	2	AstraZeneca	25	18 Years	80 Years	Alzheimer's Disease
Planning	NCT00993421	Drug	2	Eli Lilly	350	21 Years	65 Years	Obesity
Planning	NCT01000480	Drug	2	Eli Lilly	88	18 Years	N/A	Non Small Cell Lung Cancer
Planning	NCT01001104	Drug	2	Eli Lilly	144	20 Years	75 Years	Diabetes Mellitus, Type 2
Planning	NCT00996840	Drug	2	GlaxoSmithKline	90	18 Years	80 Years	Acute Respiratory Distress Syndrome
Planning	NCT00996944	Drug	2	GlaxoSmithKline	220	18 Years	79 Years	Restless Legs Syndrome
Planning	NCT01000493	Drug	2	GlaxoSmithKline	240	18 Years	64 Years	Posttraumatic Stress Disorder
Planning	NCT01000506	Biological	2	GlaxoSmithKline	604	12 Years	65 Years	Asthma
Planning	NCT01001169	Biological	2	GlaxoSmithKline	120	6 Months	17 Years	Influenza Infection
Planning	NCT00992732	Drug	2	Hemaquest	20	3 Years	N/A	Lymphoproliferative Disorders
Planning	NCT00994214	Drug	2	Ipsen	80	18 Years	75 Years	Acromegaly
Planning	NCT00993018	Drug	2	Johnson & Johnson	100	18 Years	80 Years	Diabetic Neuropathy, Painful
Planning	NCT00995449	Biological	2	Kalobios	208	18 Years	N/A	Rheumatoid Arthritis
Planning	NCT00989963	Drug	2	Lung Rx	36	18 Years	75 Years	Pulmonary Arterial Hypertension
Planning	NCT00990314	Drug	2	Lung Rx	32	18 Years	75 Years	Pulmonary Arterial Hypertension
Planning	NCT00996801	Drug	2	Merck	480	45 Years	85 Years	Osteoporosis
Planning	NCT00992173	Drug	2	Molecular Insight	100	12 Months	N/A	Neuroblastoma
Planning	NCT00992576	Drug	2	Mundipharma	600	18 Years	N/A	Constipation
Planning	NCT00995800	Drug	2	Mundipharma	60	18 Years	55 Years	Asthma
Planning	NCT00995930	Drug	2	Novartis	140	18 Years	70 Years	Prediabetic State

New Trial Registrations (Table 2 of 3)

The most recent industry sponsored clinical trials testing drugs, biologicals or medical devices registered with www.ClinicalTrials.gov registered from October 1, 2009 and still not activated (Planning) or recruiting (Recruiting) subjects on October 27, 2009.

Status	Link/ID	Type	Phase	Sponsor	Size (n)	Min age	Max age	Condition
Planning	NCT00999518	Biological	2	Pfizer	360	18 Years	N/A	Cystitis, Interstitial
Planning	NCT00988728	Drug	2	Schering-Plough	200	18 Years	N/A	Schizophrenia
Planning	NCT01001468	Drug	2	Vascular Biogenics	180	18 Years	75 Years	Active Plaque Psoriasis
Planning	NCT01001208	Drug	3	Amgen	480	18 Years	N/A	Psoriasis
Planning	NCT01001377	Drug	3	Amgen	1000	18 Years	N/A	Metastatic Colorectal Cancer
Planning	NCT00989001	Drug	3	Astellas	470	18 Years	85 Years	Atrial Fibrillation
Planning	NCT00996164	Drug	3	Boehringer Ingelheim	900	18 Years	55 Years	Sexual Dysfunctions
Planning	NCT00996372	Drug	3	Boehringer Ingelheim	900	35 Years	N/A	Sexual Dysfunctions
Planning	NCT00988208	Drug	3	Celgene	1,015	18 Years	N/A	Castrate-Resistant Prostate Cancer
Planning	NCT01001364	Drug	3	Eurofarma	80	12 Years	N/A	Asthma
Planning	NCT00992511	Biological	3	GlaxoSmithKline	268	18 Years	60 Years	Influenza Infection
Planning	NCT00992784	Biological	3	GlaxoSmithKline	526	19 Years	N/A	Influenza Infection
Planning	NCT00996125	Biological	3	GlaxoSmithKline	750	9 Years	17 Years	Hpv-16/18 Infections.
Planning	NCT01000727	Drug	3	GlaxoSmithKline	8,000	18 Years	N/A	Coronary Heart Disease
Planning	NCT01000974	Biological	3	GlaxoSmithKline	4,000	6 Weeks	12 Weeks	Epiglottitis
Planning	NCT00988221	Drug	3	Hoffmann-La Roche	185	2 Years	17 Years	Juvenile Idiopathic Arthritis
Planning	NCT00990951	Drug	3	Marjan	80	18 Years	65 Years	Constipation
Planning	NCT00988884	Biological	3	Merck	1,240	11 Years	15 Years	Human Papillomavirus Infection
Planning	NCT01001234	Drug	3	Merck	900	6 Years	17 Years	Acute Migraine.
Planning	NCT00991146	Biological	3	Novartis	20	2 Years	N/A	Multisystem Inflammatory Disease
Planning	NCT01000311	Biological	3	Novartis	520	2 Months	2 Months	Meningococcal Disease
Planning	NCT00993317	Drug	3	Otsuka	126	18 Years	75 Years	Rheumatoid Arthritis
Planning	NCT00991276	Drug	3	Pfizer	105	18 Years	60 Years	Restless Legs Syndrome
Planning	NCT00990327	Drug	3	PGxHealth	753	18 Years	N/A	Coronary Artery Disease
Planning	NCT00998686	Drug	3	Phenomix	650	18 Years	85 Years	Type 2 Diabetes Mellitus
Planning	NCT00995410	Drug	3	Pozen	400	60 Years	N/A	Aspirin-Associated Gastric Ulcers
Planning	NCT01000961	Drug	3	Raptor	20	N/A	N/A	Cystinosis
Planning	NCT00997984	Drug	3	Shire	333	6 Years	12 Years	Attention-Deficit/Hyperactivity Disorder
Planning	NCT00999206	Biological	3	Solvay Biologicals	3,006	18 Years	N/A	Influenza
Planning	NCT00996281	Drug	3	Takeda	880	18 Years	N/A	Essential Hypertension
Planning	NCT00994318	Drug	3	Vifor	1,016	18 Years	N/A	Chronic Kidney Disease
Planning	NCT00996918	Drug	3	Wyeth	1,000	N/A	N/A	Alzheimer Disease
Planning	NCT00998764	Drug	3	Wyeth	800	N/A	N/A	Alzheimer Disease
Planning	NCT00993109	Drug	4	Bayer	356	18 Years	75 Years	Hypertension
Planning	NCT01000805	Drug	4	Eli Lilly	520	18 Years	N/A	Major Depressive Disorder
Planning	NCT00988637	Drug	4	Galderma	120	18 Years	80 Years	Plaque Psoriasis
Planning	NCT00992407	Drug	4	Janssen	160	18 Years	55 Years	Psychotic Disorders
Planning	NCT00993187	Drug	4	Merck	330	18 Years	N/A	Diabetes Mellitus, Non-Insulin-Dependent
Planning	NCT00997477	Drug	4	Novartis	110	18 Years	N/A	Asthma
Planning	NCT00993915	Drug	4	Pfizer	700	18 Years	80 Years	Coronary Artery Disease
Planning	NCT00994461	Drug	4	Pfizer	185	40 Years	74 Years	Healthy
Planning	NCT00998309	Drug	4	Pfizer	360	N/A	N/A	Bacterial Infections
Planning	NCT00992394	Drug	4	Wyeth	298	18 Years	N/A	Psoriasis
Planning	NCT00997503	Device	4	Boston Scientific	4,200	18 Years	N/A	Coronary Artery Disease
Recruiting	NCT00996957	Biological	1	Acceleron	66	18 Years	N/A	Multiple Myeloma
Recruiting	NCT00992381	Drug	1	AstraZeneca	24	18 Years	55 Years	Healthy
Recruiting	NCT00995787	Drug	1	AstraZeneca	20	30 Years	75 Years	Type 1 Diabetes Mellitus
Recruiting	NCT00997308	Drug	1	AstraZeneca	45	65 Years	85 Years	Healthy
Recruiting	NCT00993499	Drug	1	Boehringer Ingelheim	42	18 Years	N/A	Carcinoma, Non-Small-Cell Lung
Recruiting	NCT00999401	Drug	1	Cyclacel	40	18 Years	N/A	Advanced Solid Tumors
Recruiting	NCT00991718	Drug	1	Genentech	12	18 Years	65 Years	Healthy
Recruiting	NCT00999531	Drug	1	Gilead	24	18 Years	65 Years	Airway Hydration
Recruiting	NCT00996021	Drug	1	GlaxoSmithKline	40	18 Years	55 Years	Healthy Subjects
Recruiting	NCT01000597	Drug	1	GlaxoSmithKline	80	20 Years	64 Years	Asthma
Recruiting	NCT00991107	Drug	1	Hollis-Eden	6	18 Years	65 Years	Insulin Resistance
Recruiting	NCT00990938	Drug	1	Idera	50	18 Years	70 Years	Hepatitis C
Recruiting	NCT01001013	Drug	1	LG Life	24	20 Years	45 Years	Healthy
Recruiting	NCT00992745	Drug	1	Molecular Insight	12	18 Years	N/A	Prostate Cancer
Recruiting	NCT00992537	Drug	1	Novo Nordisk	27	18 Years	65 Years	Diabetes Mellitus, Type 1
Recruiting	NCT00993096	Drug	1	Novo Nordisk	33	18 Years	65 Years	Diabetes Mellitus, Type 1
Recruiting	NCT00993304	Drug	1	Novo Nordisk	20	18 Years	75 Years	Diabetes Mellitus, Type 2
Recruiting	NCT00988624	Drug	1	Pfizer	20	18 Years	55 Years	Huntington Disease
Recruiting	NCT00999015	Drug	1	Pfizer	27	18 Years	55 Years	Healthy
Recruiting	NCT00990223	Drug	1	Pfizer	20	18 Years	55 Years	Healthy
Recruiting	NCT00991016	Drug	1	Pfizer	61	21 Years	55 Years	Healthy

New Trial Registrations (Table 3 of 3)

The most recent industry sponsored clinical trials testing drugs, biologicals or medical devices registered with www.ClinicalTrials.gov registered from October 1, 2009 and still not activated (Planning) or recruiting (Recruiting) subjects on October 27, 2009.

Status	Link/ID	Type	Phase	Sponsor	Size (n)	Min age	Max age	Condition
Recruiting	NCT00999336	Drug	1	Portola	32	18 Years	80 Years	Renal Impairment
Recruiting	NCT01001351	Drug	1	Proteon	36	18 Years	N/A	Chronic Kidney Disease
Recruiting	NCT00998933	Drug	1	Solvay	24	18 Years	80 Years	Hypogonadal
Recruiting	NCT00988533	Drug	1	Topaz	30	6 Months	3 Years	Head Lice
Recruiting	NCT00997100	Drug	2	Active Biotech	20	18 Years	N/A	Systemic Lupus Erythematosus
Recruiting	NCT00997152	Drug	2	Akros	150	18 Years	70 Years	Type II Diabetes Mellitus
Recruiting	NCT00998946	Drug	2	Allos	27	18 Years	N/A	Lymphoma, B-Cell
Recruiting	NCT00991861	Drug	2	Almirall	100	18 Years	N/A	Actinic Keratosis
Recruiting	NCT01001338	Drug	2	Ardea	108	18 Years	75 Years	Gout
Recruiting	NCT00994292	Drug	2	Astellas	1,264	18 Years	N/A	Acute Coronary Syndrome
Recruiting	NCT00999466	Drug	2	AstraZeneca	59	18 Years	55 Years	Allergic Asthma
Recruiting	NCT00991796	Drug	2	Daiichi Sankyo	100	18 Years	N/A	Non-Small Cell Lung Cancer
Recruiting	NCT00992225	Drug	2	Eli Lilly	40	18 Years	N/A	Breast Cancer
Recruiting	NCT00989612	Biological	2	GlaxoSmithKline	100	20 Years	64 Years	Influenza Infection
Recruiting	NCT00999167	Drug	2	Hyperion	Missing	18 Years	65 Years	Hepatic Encephalopathy
Recruiting	NCT00999830	Drug	2	Innate	42	18 Years	75 Years	Multiple Myeloma
Recruiting	NCT00996476	Drug	2	Janssen	84	20 Years	70 Years	Hepatitis C, Chronic
Recruiting	NCT00995904	Drug	2	MAP	24	4 Years	11 Years	Asthma
Recruiting	NCT00994097	Drug	2	Molmed Spa	102	18 Years	N/A	Non-Small Cell Lung Cancer
Recruiting	NCT00992212	Biological	2	Novartis	400	18 Months	N/A	Pandemic Influenza Disease
Recruiting	NCT00996307	Biological	2	Novartis	688	6 Months	35 Months	Influenza
Recruiting	NCT00993226	Drug	2	Nycomed	224	18 Years	N/A	Postoperative Pain
Recruiting	NCT00993798	Drug	2	Nycomed	224	18 Years	N/A	Postoperative Pain
Recruiting	NCT00998192	Biological	2	Oncolytics	55	18 Years	N/A	Carcinoma
Recruiting	NCT00998322	Biological	2	Oncolytics	33	18 Years	N/A	Metastatic Pancreatic Adenocarcinoma
Recruiting	NCT00989573	Drug	2	Otsuka	180	16 Years	64 Years	Crohn's Disease
Recruiting	NCT00997282	Drug	2	Otsuka	255	20 Years	74 Years	Diabetes Type 2
Recruiting	NCT00988143	Biological	2	Sanofi-Aventis	598	6 Months	N/A	Influenza
Recruiting	NCT00988507	Drug	2	Sanofi-Aventis	440	N/A	N/A	Plasmodium Falciparum Infection
Recruiting	NCT00993382	Drug	2	Sanofi-Aventis	486	21 Years	N/A	Arrhythmia Prophylaxis
Recruiting	NCT00993447	Biological	2	Sanofi-Aventis	600	9 Years	16 Years	Dengue Fever
Recruiting	NCT00988936	Drug	2	Siemens	40	18 Years	N/A	Non-Small Cell Lung Cancer
Recruiting	NCT00994422	Drug	2	Topaz	250	2 Years	N/A	Head Lice
Recruiting	NCT00991068	Drug	2	ZARS	20	18 Years	N/A	Carpal Tunnel Syndrome
Recruiting	NCT01001494	Drug	3	Almirall	810	40 Years	N/A	Chronic Obstructive Pulmonary Disease
Recruiting	NCT00988156	Drug	3	Bial - Portela	252	2 Years	16 Years	Partial Epilepsy
Recruiting	NCT00988429	Drug	3	Bial - Portela	360	16 Years	N/A	Partial Epilepsy
Recruiting	NCT00996658	Drug	3	Boehringer Ingelheim	290	18 Years	79 Years	Diabetes Mellitus, Type 2
Recruiting	NCT00996216	Drug	3	GlaxoSmithKline	340	18 Years	N/A	Thrombocytopaenia
Recruiting	NCT00996606	Drug	3	Hoffmann-La Roche	70	18 Years	N/A	Rheumatoid Arthritis
Recruiting	NCT00992459	Drug	3	Hyperion	Missing	18 Years	N/A	Urea Cycle Disorders
Recruiting	NCT00993681	Biological	3	Intercell	1,800	18 Years	64 Years	Travelers' Diarrhea
Recruiting	NCT00997204	Drug	3	Jerini	150	18 Years	N/A	Hereditary Angioedema
Recruiting	NCT00998881	Drug	3	Mitsubishi	200	20 Years	75 Years	Type 2 Diabetes Mellitus
Recruiting	NCT00989989	Drug	3	Novartis	390	18 Years	N/A	Diabetic Macular Edema
Recruiting	NCT00995709	Biological	3	Novartis	102	18 Years	N/A	Behcet Disease
Recruiting	NCT00999908	Drug	3	Novartis	63	40 Years	N/A	Chronic Obstructive Pulmonary Disease
Recruiting	NCT01001572	Drug	3	Novartis	566	18 Years	85 Years	Essential Hypertension
Recruiting	NCT00993473	Drug	3	Sanofi-Aventis	90	1 Year	6 Years	Type 1 Diabetes Mellitus
Recruiting	NCT00993967	Drug	3	Santhera	204	9 Years	N/A	Freidreich's Ataxia
Recruiting	NCT00994786	Drug	4	Hamilton	66	18 Years	65 Years	Obsessive-Compulsive Disorder
Recruiting	NCT00996203	Drug	4	Hoffmann-La Roche	200	18 Years	N/A	Rheumatoid Arthritis
Recruiting	NCT01000610	Drug	4	Hoffmann-La Roche	20	18 Years	N/A	Rheumatoid Arthritis
Recruiting	NCT00994851	Drug	4	Sanofi-Aventis	120	18 Years	59 Years	Constipation
Recruiting	NCT00998673	Device	2	Bayer	250	18 Years	N/A	Venous Ulcer
Recruiting	NCT00991120	Device	2	Medtronic	93	18 Years	N/A	Heart Failure
Recruiting	NCT00992680	Device	2	Rox	48	18 Years	80 Years	Chronic Obstructive Pulmonary Disease
Recruiting	NCT00998790	Device	4	American Medical Systems	115	40 Years	N/A	Urinary Incontinence, Stress
Recruiting	NCT00998660	Device	4	Medtronic	100	7 Years	N/A	Dystonia
Recruiting	NCT00990340	Device	4	Teva	53	7 Years	17 Years	Growth Hormone Deficiency

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