

Thailand Towards Excellence in Clinical Trials
13th ThaiTECT Annual Conference “Speed with Quality”
13-14 June 2013 (Draft 2 May 2013)

Miracle Grand Convention Hotel Bangkok, Thailand

Target audience includes all stakeholders in clinical trials in Thailand e.g. investigators, ethic committees, research institutes, sponsors, CROs, and regulators, etc.

Languages : Thai, except International speakers will present in English (NO simultaneous translation)

13 June 2013 (Day 1)	
08.30-09.00	Registration
09.00-09.15	Opening Remark: <i>Dr.Boonchai SOMBOONSOOK,M.D., Secretary General of Thai FDA</i>
09.15-09.45	Keynote speaker “Government strategy and action to foster value chain of new drug development” <i>Dr.Boonchai SOMBOONSOOK,M.D., Secretary General of Thai FDA</i>
09.45-10.00	Thai TECT Award
10.00-10.15	Coffee/ Tea break
10.15-11.15	“Towards Global Quality Clinical Trial” Moderator: <i>Dr.Suchart CHONGPRASERT, Ph.D., Thai FDA</i> - Application of Quality System towards GCP and International Standards for Clinical Trial Sites <i>Prof.Dr.Suwat CHARİYALERTSAK, M.D., Director, Research Institute for Health Sciences, RIHES</i> - Rigorous Quality Review and Monitoring of Clinical Trials by Ethic Committee : Real Life Experience for Monitoring Protocol Compliance and Subject Protection <i>Dr.Supachai RERK-NGARM, M.D.,Senior Expert In Prevention Medicine,EC-MOPH</i>
11.15-12.15	“Preparation for Clinical Trial Phase I” Moderator: <i>Dr.Yuppadee JAVROONGRIT, Ph.D., Thai FDA</i> - Regulatory criteria, role and quality management: CRO’s perspective <i>Ms.Renate SCHIRROW, Aclires</i> - Ethical review process for phase I clinical trial <i>Prof.Dr. Sasithon PUKRITTAYAKAMEE,M.D., FERCIT</i>
12.15-13.15	Lunch Break
13.15-14.00	“WHO NRA strengthening programme: oversight of clinical trials, expected standards and challenges for vaccines regulation including prequalification” <i>Mr.Lahouari BELGHARBI, WHO</i>

14.00-15.00	<p>“Success story: Imojev[®] vaccine”</p> <p>Moderator: <i>Ms.Prapassorn THANAPHOLLERT, Thai FDA</i></p> <ul style="list-style-type: none"> - Clinical development in Pediatric Population <i>Dr. Sunate CHUENKITMONGKOL, M.D., Sanofi-Pasteur</i> - Manufacturing Development <i>Dr.Jean-Baptiste NICOLLET, M.D., Sanofi-Pasteur</i>
15.00-15.15	Coffee/ Tea break
15.15-15.45	<p>“Update in CREC operation and Inform Consent in Children”</p> <p><i>Assoc. Prof.Dr. Aphronpirom KETUPANYA, M.D., FERCIT</i></p>
15.45-16.15	<p>“Updates on EC’s recognitions”</p> <p><i>Mr. Vinit USAVAKIDVIREE, Thai FDA</i></p>
16.15-16.30	Q & A

14 June 2013 (Day 2)	
08.30-09.00	Registration
09.00-10.15	<p>“Updates on Human Research Act”</p> <p>Moderator: <i>Dr.Pravich THANYASITTISUNTORN, M.D.</i></p> <ul style="list-style-type: none"> - <i>Dr.Chanvit THARATHEP, M.D., Deputy Permanent Secretary</i> - <i>Prof. Dr. Soottiporn CHITTMITRAPAP, M.D., Secretary General of NRCT</i>
10.15-10.30	Coffee/ Tea break
10.30-12.30	<p>“Country Updates and Approaches towards the Vision”</p> <p>Moderator: <i>Dr. Sudhichai CHOKEKIJCHAI, M.D.</i></p> <ul style="list-style-type: none"> - Thai Food and Drug Administration’s representative <i>Dr.Pathom SAWANPANYALERT, M.D., Ph.D., Deputy Secretary General, Thai FDA</i> - Investigators’s representative <i>Prof.Dr.Pyatat TATSANAVIVAT, M.D., MedResNet</i> - Sponsors’s representative <i>Dr.Sunetra CHINNAPHA, M.D., PReMA</i> - Ethic Committees’s representative <i>Assoc. Prof. Dr.Nimit MORAKOT, M.D., FERCIT</i> - EC Accreditation Body’s representative <i>Assoc. Prof.Sopit THAM-AREE, NECAST</i>
12.30-13.30	Lunch break
13.30-14.00	<p>“Result of APEC’s Questionnaire to Promote GCP Inspection”</p> <p><i>Ms. Akanid WAPEEWUTTIKORN, Thai FDA</i></p>

14.00-15.00	“Regulatory Inspection Trend & Common pitfall : Sponsor ’s perspective” <i>Ms. Maggie Lim, GSK</i>
15.00-15.15	Coffee/ Tea break
15.15-15.45	“Conclusion and Our way forward” <i>Prof.Dr. Kiat RUXRUNGTHAM,M.D., Chairman of ThaiTECT</i>
15.45-16.00	Closing & invitation to 2014 ThaiTECT by <i>Assoc.Prof.Jaakchai JUNGTHIRAPANICH,M.D. (Thammasart university) (TBC)</i>

List of Abbreviations

- **ThaiTECT** Thailand Towards Center of Excellence in Clinical Trials
- **Thai FDA** Thai Food And Drug Administration
- **FERCIT** Forum for Ethical Review Committees in Thailand
- **WHO** World Health Organization
- **RIHES** Research Institute for Health Sciences, Chiangmai University
- **EC-MOPH** Ethical Review Committee for Research in Human Subjects,
Ministry of Public Health
- **GSK** GlaxoSmithKline
- **APEC** Asia Pacific Economic Cooperation
- **NECAST** National Ethics Committee Accreditation System in Thailand
- **MedResNet** Medical Research Network of the Consortium of Thai Medical Schools
- **NRCT** National Research Council of Thailand
