



# 16<sup>th</sup> ThaiTECT Annual Meeting 2016

“From Pre-Clinical to Early Phase Clinical Trials:  
Challenges and Opportunities in Translational Research”

4 – 5 August 2016

The Sukosol Hotel, Bangkok

## Day 1: 4 August 2016

08.30 - 09.00

Registration

09.00 - 09.15

### Welcome Remarks

- Clinical Professor Udom Kachintorn, M.D.,  
President of Mahidol University

### Moderator:

- TBC

09.15 - 09.45

### Opening Remarks and Ministry Keynote Speech:

**"Policy challenges for medical product development in Thailand"**

### Opening Remarks:

- Clinical Professor Piyasakol Sakolsatayadorn, M.D.,  
Minister of Public Health (TBC)

### Keynote Speech:

- Professor Dr. Yongyuth Yuthavong  
Former Deputy Prime Minister, Former Minister of Science  
and Technology and Senior specialist to NSTDA

### Moderator:

- Professor Yaowalark Sukthana, M.D.,  
Dean of the Faculty of Tropical Medicine, Mahidol University

09.45 - 10.30

**Translational Research from Bench to Clinic: Lessons Learnt from  
Pasteur Institute, Paris**

- Dr. Anavaj Sakuntabhai, M.D.,  
Pasteur Institute, Paris

**Moderator:**

- Dr. Nares Damrongchai,  
CEO of Thailand Center of Excellence for Life Sciences

10.30 - 10.45

**Group Photography and Coffee Break**

**Session I: Manufacturing Aspects for Investigational products**

10.45 - 11.45

**Chemical Manufacturing Control for Submission (CMC)**

- ACLIRES

**Moderator:**

- PReMA

**Manufacturing for Investigational products**

- TBC

**Moderator:**

- PReMA

11.45-12.45

**Lunch**

**Session II: Gaps and Opportunities in Moving Candidate Vaccine from Pre-Clinical Studies to Phase I Clinical Trials**

12.45 - 15.00

- Associate Professor Dr. Parntep Ratanakorn,  
Dean of the Faculty of Veterinary Science,  
Mahidol University
- Professor Dr. Prasert Auewarakul,  
Director of Institute of Molecular Biosciences,  
Mahidol University
- Mrs. Teeranart Jivapaisarnpong,  
Former Director of Institute of Biological Products,  
Department of Medical Sciences, Ministry of Public Health

**Moderator:**

- Ms. Sumol Pavittranon,  
Specialist, Thailand Center of Excellence for Life Sciences  
(TCELS)

15.00 - 15.30

**Open Discussion**

**Day 2: 5 August 2016**

- 08.30 - 09.00 Registration
- 09.00 – 09.45 **Keynote Speech: Lessons Learnt from Clinical Development to Licensure**
- Professor Myron M. Levine, M.D.,  
Associate Dean, School of Medicine, University of Maryland
- Moderator:**
- Professor Punnee Pitisuttithum, M.D.,  
Faculty of Tropical Medicine, Mahidol University
- 9.45 – 10.00 **Report from Clinical Research Impact Study**
- PReMA
- Moderator:**
- TBC
- 10.00 - 10.10 **Outstanding Institutional Review Board/Independent Ethics Committee (IRB/IEC) 2016 Awards  
Outstanding Clinical Research Center (CRC) 2016 Awards  
Group Photography**
- Moderator:**
- TBC
- Session III: Phase I&II Vaccine and Monoclonal Antibody Designs and Advancement Criteria**
- 10.10 - 10.30 **Vaccine Clinical Development**
- Shibadas Biswal, M.D.,  
Associate Medical Director Dengue.  
Takeda Vaccines Pte, Ltd.
- Moderator:**
- Professor Dr. Kiat Ruxrungtham, M.D.,  
Faculty of Medicine, Chulalongkorn University
- 10.30 – 10.50 **State of the Art: Monoclonal Antibody Development**
- Dr. Songpon Deechongkit,  
Managing Director of Siam Bioscience Co., Ltd.
- Moderator:**
- Pravich Tanyasittisuntorn, M.D.,  
Director of Medical Research Network of the Consortium  
of the Thai Medical Schools

10.50 -11.20

### **Ethical Aspects in Moving Product to Phase I**

- TBC  
Siriraj Institutional Review Board, Faculty of Medicine  
Siriraj Hospital, Mahidol University
- Associate Professor Pope Kosalaraksa,  
Faculty of Medicine, Khon Kaen University

#### **Moderator:**

- Associate Professor Jaakchai Jungthirapanich, M.D.,  
Forum for Ethical Review Committees in Thailand

11.20 – 12.00

### **Lessons Learnt from Biopharmaceutical Phase I Trial in Japan**

- TBC (Japanese Expert)

#### **Moderator:**

- Food and Drug Administration, Ministry of Public Health

12.00 - 13.00

Lunch

13.00 – 13.40

### **Thai Regulatory Updates for Phase I**

- TBC  
Food and Drug Administration, Ministry of Public Health
- Mrs. Teeranart Jivapaisarnpong,  
Former Director of Institute of Biological Products,  
Department of Medical Sciences, Ministry of Public Health

#### **Moderator:**

- TBC

13.40 – 14.00

Q&A

## **Session IV: Opportunities and Future for Thailand in Translational Research**

14.00 - 15.00

### **symposium: Current and Future R&D in Biopharmaceutical Products**

- TBC  
Chulalongkorn University
- TBC  
Mahidol University
- TBC  
Thammasat University
- TBC  
King Mongkut's University of Technology Thonburi
- TBC  
Department of Medical Sciences, Ministry of Public Health
- Dr.Nares Damrongchai,  
CEO, Thailand Center of Excellence for Life Sciences

#### **Moderator:**

- National Research Council Thailand

15.00 - 15.15

**Meeting Summary and way forward**

- Professor Yaowalark Sukthana, M.D.,  
Dean of the Faculty of Tropical Medicine, Mahidol University
- Professor Kiat Ruxrungtham, M.D.,  
Chairman of ThaiTECT

**Moderator:**

- TBC

15.15 - 15.30

**Handover of ThaiTECT Annual Meeting in 2017 to Bangkok Health Research Center and Closing Remarks**

- Professor Yaowalark Sukthana, M.D.,  
Dean of the Faculty of Tropical Medicine, Mahidol University
- Dr. Chaiyos Kunanusont,  
Director of Bangkok Health Research Center

**Moderator:**

- TBC