



16th 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