



2021 年六月份會議

日期：2021 年 6 月 23 日 (星期三)

地點：(WebEX 視訊方式)

議程：

時 間	主 題	主 講 人
13:15 ~ 13:30	請提早上線，以確保準時加入會議	
13:30 ~ 13:50	會務報告	黃麗榕 理事長
13:50 ~ 14:30	Task Force 報告	Task Force Leads & Co-Leads ♦ EC – Hockey /Vivi/Claire/Anchi ♦ C&C – Muting /Ariel/Zoe/Carol ♦ GA – Iris /Mandy/Cherri/Lee-Hsin ♦ EDU – Tina /Emily/Molly
14:30~14:50	臨時動議 & Wrap up	黃麗榕 理事長
14:50 ~ 15:20	專題演講 I ❖ COVID-19 Vaccines / EUA vs. BLA	陳慧玲 博士
15:20 ~ 15:30	Break	
15:30 ~ 17:00	專題演講 II ❖ 疫苗臨床試驗的統計考量 Statistical Considerations in Vaccine Clinical Trials	張啟仁 特聘教授 長庚大學臨床資訊與醫學統計 研究中心

Speaker Introduction :

陳慧玲 博士 Elinor Chen Ph.D.

Dr. Elinor Chen has been an independent strategic regulatory consultant since 2014. Prior to that, she spent more than 25 years working in Merck & Co., holding a number of roles with increasing responsibility, including a 3-year stint as Senior Advisor to the Head of Clinical Development at MSD-Japan and a 2.5 year stint in MSD-Taiwan as Head of Regulatory and Clinical Development.

At Merck, Dr. Chen managed the regulatory strategy for programs involving multiple therapeutic areas, served as a Regulatory Lead or Advisor for multi-disciplinary project teams and involved with products at all stages of clinical development. She also served on worldwide business strategy committees across therapeutic areas. Dr. Chen has extensive experience in strategic interactions with global regulatory authorities such as FDA, EMA and PMDA, for new product development and registration, managing a positive FDA advisory committee meeting, and global filings of all types of regulatory submissions.

Prior to her career at Merck, Dr. Chen spent 4 years at BMS as a Group Leader in controlled release formulation R&D.

Dr. Chen received her B.S. in pharmacy from National Taiwan University, and Ph.D. in Pharmaceutical Chemistry from University of Michigan at Ann Arbor, Michigan.



張啟仁 特聘教授 Chee-Jen Chang, Ph.D. /長庚大學臨床資訊與醫學統計研究中心

Education :

Ph.D. Department of Statistics, University of Iowa, Iowa City, Iowa. 1991.

M.S. Department of Mathematics, University of Iowa, Iowa City, Iowa. 1985.

B.S. Department of Applied Mathematics, National Chiao Tung University, Taiwan. 1979.

Professional Experiences :

Chair Elect (2017~2019), Advisory Committee, International Society for Pharmacoeconomics and Outcome Research Asia Consortium.

President (2013~2018), Taiwan Society for Pharmacoeconomics and Outcome Research

President (2013~2018), International Society for Pharmacoeconomics and Outcome Research, Taiwan Chapter.

Member of Editorial advisory board (2015~current), Value in Health Regional Issue for Asia Issues.

Co-Editor (2014~2018) News Across Asia, ISPOR Asia Consortium Newsletter.

Chair (2012~2018) Publication Committee, ISPOR Asia Consortium.

Director (2013~current) Research Services Center for Health Information, Chang Gung University.

Director (2009~current) Clinical Informatics and Medical Statistics Research Center, Chang Gung University.

Distinguished Professor (2019~current) Graduate Institute of Clinical Medical Science, Chang Gung University.

Adjunct Professor (2019~current) Department of Biomedical Sciences, Chang Gung University.

Professor (2005~2019) Graduate Institute of Clinical Medical Science, Chang Gung University.

Director (2005~2018) Statistical Center for Clinical Research, Chang Gung Memorial Hospital.

Professor (2005~2006) Graduate Institute of Basic Medical Science, Chang Gung University.

Adjunct Professor (2007~2018) Graduate Institute of Medical Mechatronics, Chang Gung University.

Adjunct Professor (2005~current) Graduate Institute of Clinical Medicine and Graduate Institute of Clinical Pharmacy, School of Medicine, National Taiwan University.

Director (2003~2005) Bioinformatics and Biostatistics Core, National Taiwan University Center for Genomic Medicine.

Deputy Director (2000~2005) Clinical Trial Center, National Taiwan University Hospital.

Associate Research Fellow (2000~2005) Division of Clinical Medicine, National Taiwan University Hospital, School of Medicine, National Taiwan University.

Adjunct Associate Professor (2000~2005) Graduate Institute of Clinical Medicine and Graduate Institute of Clinical Pharmacy, National Taiwan University School of Medicine.

Biostatistical Core Director (1997~2000) General Clinical Research Center, Albert Einstein College of Medicine.

Director (1997~2000) Biostatistics Core, Comprehensive Cancer Center, Albert Einstein College of Medicine

Associate Professor (1997~2000) Division of Epidemiology and Biostatistics, Department of Epidemiology and Social Medicine, Albert Einstein College of Medicine.



Adjunct Senior Lecturer (1998~1999) Graduate School of Health Sciences, New York Medical College.

Director (1996~2000) Biostatistical Facility, Albert Einstein College of Medicine

Assistant Professor (1992~1997) Division of Epidemiology and Biostatistics, Department of Epidemiology and Social Medicine, Albert Einstein College of Medicine.

Instructor (1991~1992) Division of Epidemiology and Biostatistics, Department of Epidemiology and Social Medicine, Albert Einstein College of Medicine.

Senior Statistical Consultant (1989~1991) Statistical Consultant Center, University of Iowa.

Instructor (1988~1989) Department of Statistics and Actuarial Science, University of Iowa.

Research Assistant (1983~1988) Department of Statistics and Actuarial Science, University of Iowa.

System Analyst / Programmer (1979~1983) Department of Information System, Computer Center, The Bank of Taiwan, Taipei, Taiwan.