台灣藥物臨床研究協會
Taiwan Clinical Research Association

2025 年十一月份會議暨第十屆第一次會員大會

日期：2025 年 11 月 27 日 (星期四)

地點：中國文化大學建國本部(大夏館) 國際會議廳 (台北市建國南路二段 231 號 B1)

議程：

時　間	主　　題	主講人
13:00 ~ 13:30	報到	
13:30 ~ 13:40	**1) 會務報告**	**孫婷婷 理事長**
13:40 ~ 14:30	**2) Task Force 報告**	**Task Force Leads** & Co-Leads ♦ GA – **Muting**/Carol/Mandy/Nicole ♦ EC – **Sharon**/Anna/Curtis ♦ C&C – **Lillian**/Jessie/Leila/Nora/Tracy ♦ EDU – **Vivi**/Mandy/Patty/Stephen ♦ BTT – **Alice**/Nora
14:30 ~ 14:40	**3) 提案討論** **4) 臨時動議** **5) 第十屆理監事選舉流程說明**	**孫婷婷 理事長**
14:40 ~ 15:00	**6) 投票** & Break	
15:00 ~ 16:30	**7) 專題演講** ❖ Modernizing Dose-Finding and Considerations Related to Dose Optimization in Early Phase Clinical Research for Oncology Drug Development	**Carlos Linn, MD** Global Lead Clinician | Medical Monitor | Sr. Director | Global Clinical Development | Pfizer Research and Development
16:30 ~ 17:00	**8) 第十屆理監事選舉開票**	

➢ Speaker Introduction

Carlos Linn, MD / Global Lead Clinician | Medical Monitor | Sr. Director | Global Clinical Development | Pfizer Research and Development

Carlos Linn, MD. is currently serving as a Global Lead Clinician and Medical Monitor at Pfizer's Oncology Research and Development division. Since 2017, he has been deeply involved in the global clinical development, safety surveillance, and medical governance of Pfizer's oncology portfolio. The responsibilities span across Phase 1a/b, 1/2, 2, and 3 studies in oncology, immuno-oncology, and hematologic malignancies. He had been involved in the development of investigational products such as gemtuzumab ozogamicin, talazoparib, avelumab, and sasanlimab. More recently, he has been serving as the lead clinician and/or medical monitor for several cutting-

edge programs, including CD47 blocker fusion proteins (ontorpacept and maplirpacept) in Phase 1 and 1/2 studies for hematologic malignancies and ovarian cancer, bispecific BCMA antibody (elranatamab) Phase 1/2 studies for refractory and relapsed multiple myeloma, palbociclib PATINA study for HR+/HER2+ breast cancer, felmetatug vedotin for triple-negative breast cancer (TNBC), CDK2/CDK4 inhibitors (tagtociclib and atirmociclib) and HER2 TKI (tucatinib) Phase 1, 2 studies for metastatic breast cancer.

Before current role, he was the Clinical Development Lead for Oncology at Pfizer Development China between 2014 and 2017, and a team of five clinicians executing China-specific oncology programs sourced from global pipelines including crizotinib for 1st-line ALK+ NSCLC in China/Asia, Phase 1 and 3 palbociclib studies for breast cancer in China/East Asia, Phase 2 and 3 lorlatinib studies for 1st- and 2nd-line NSCLC.

He received the Doctor of Medicine (M.D.) from National Yang-Ming Medical College (now National Yang-Ming Chiao-Tung University) in 1993, followed by residency in obstetrics and gynecology and fellowship in gynecologic oncology at Taipei Veterans General Hospital. He became an attending physician and board-certified gynecologic oncologist in 2002. Since 2004, he has held an adjunct academic position at National Yang-Ming University and has contributed to the Taiwan Cooperative Oncology Group (TCOG) and National Health Research Institute (NHRI) as an editorial panelist for the Consensus & Guidelines in Gynecologic Cancers, with three editions published since 2003 (ISBN: 978-986-02-8017-3).

He began his pharmaceutical career at Eli Lilly Taiwan as an Oncology Clinical Research Physician in 2005. He was promoted to Intercontinental Regional Clinical Research Physician in 2008 and to Senior Regional Medical Advisor for clinical Development & medical Affairs in the Emerging Market Business Unit (EMBU) in 2009. He joined Pfizer in 2012 as Regional Medical Director for Oncology in Emerging Markets Asia and China, then transitioned to Development China in 2014, and has been dedicating to oncology/hematology global clinical development since 2017.

Beyond his professional roles, he is an active speaker and educator. Over the past four years, he delivered more than 15 non-corporate professional talks on early-phase oncology study design and immunotherapy at academic institutions, university hospitals, and national/regional cancer societies. He provided educational courses such as Female Cancer Management, Physician Scientist, and Clinical Research Overview at National Yang-Ming Chao-Tung University and was honored with the Best Teacher Awards in 2022, 2023, and 2024. He maintains strong professional networks and long-term collaborations with cancer-treating physicians, investigators, institutions, and professional societies across the Asia-Pacific region, the EU, and the United States. As of September 2025, he has been the author of 17 more articles published in the peer-reviewed SCI journals.

➢ Abstract

Historically, dose-finding trials in oncology have focused on identifying the maximum tolerated dose (MTD) and the recommended phase 2 dose (RP2D), alongside a preliminary evaluation of antitumor activity at the RP2D. The MTD is typically determined by escalating doses in small patient cohorts until a predefined rate of severe or life-threatening dose-limiting toxicities (DLTs) is observed. Subsequent trials often proceed with the RP2D, usually equivalent or close to the MTD without further dosage refinement.

This traditional paradigm, rooted in the development of cytotoxic chemotherapies, prioritizes rapid drug availability for patients with limited treatment options and accepts substantial toxicity as a trade-off for potential efficacy. However, it often overlooks critical factors such as low-grade symptomatic toxicities, the need for dose modifications, dose- and exposure-response relationships, and variability across specific patient populations (e.g., by age, organ function, or comorbidities).

For targeted therapies, such as kinase inhibitors, monoclonal antibodies, and antibody-drug conjugates (ADC), the dose-response relationship may differ significantly from cytotoxic agents. These therapies often achieve similar efficacy at doses below the MTD, with reduced toxicity. In

some cases, the MTD may not be reached, and serious adverse events may emerge only after prolonged treatment. Given that patients may remain on targeted therapies for extended periods, chronic low-grade toxicities can impair quality of life and limit treatment adherence, ultimately affecting therapeutic outcomes.

Recognizing these challenges, the FDA Oncology Center of Excellence launched Project Optimus in 2021 to reform the dose optimization paradigm in oncology. This initiative promotes collaboration among industry, academia, regulatory bodies, professional societies, and patients to identify optimized dosages that balance efficacy and safety.

As of August 2024, the FDA's guidance titled Optimizing the Dosage of Human Prescription Drugs and Biological Products for the Treatment of Oncologic Diseases outlines current regulatory expectations for dose optimization. Since then, dosage refinement beyond initial dose escalation has become a central focus in early-phase oncology trials. Both the FDA and EMA now strongly encourage integrating dose optimization strategies to enhance the safety, efficacy, and tolerability of new cancer therapies.