

ESMO ADVANCED COURSE PROGRAMME EARLY DRUG DEVELOPMENT

17-18 July 2025
Hong Kong

CO-CHAIRS:	Jayesh Desai, Australia Elena Garralda, Spain Brigette Ma, Hong Kong SAR, China	SPEAKERS:	Boon Cher Goh, Singapore Bruno Gomes, Switzerland Ezogelin Gruyters, United States Dirk Laurent, Germany Ruth Plummer, United Kingdom Lilian L. Siu, Canada Anastasios Stathis, Switzerland Daniel S. W. Tan, Singapore Ben Tran, Australia Timothy A. Yap, United States
-------------------	---	------------------	--

LEARNING OBJECTIVES

- To foster, educate and mentor the next generation of Phase I/Early Drug Development Programmes in Oncology centres from both the established and emerging economies in the Asia-Pacific region.
- To understand the fundamentals to establishing and running a successful Phase I/Early Drug Development Programme: from an in-depth understanding of trial selection to patient coordination, to running a programme, to effectively engaging with sponsors and fellow PIs, regional and international engagement, regulatory processes.
- To bridge the gap between the key stakeholders in the drug development process in the Asia-Pacific region: investigators, sponsors (Pharma and Biotech), Contract Research Organization (CRO), regulatory bodies.

Thursday, 17 July 2025

- 08:30-08:40 **Welcome and course overview**
Jayesh Desai, AU, Elena Garralda, ES and Brigitte Ma, HK SAR, CN
- 08:40-09:40 **Session 1 – Round table introductions: Meet the Faculty and Attendees**
Faculty members will be assigned to a group of delegates (10+3 co-chairs): 3 faculty/per group (4 groups)
Mutual introduction by faculty and participant of their respective research area/ interests and institutions, discuss details on course content, objectives and what is expected of participants.

- 09:40-10:40 **Session 2 – Phase I clinical trial design & methods**
Co-Chairs: Jayesh Desai, AU and Elena Garralda, ES
- 20' The Importance of the phase I trial in the drug development process.
Successes and lessons learned
Lilian Siu, CA
- 20' Current designs of phase 1 clinical trials and Limitations
Ruth Plummer, UK
- 20' Q&A
- 10:40-11:10 **Coffee break**
- 11:10-12:05 **Session 3 – Considerations in evaluating key drug classes and the protocol**
Co-Chairs: Elena Garralda, ES and Brigitte Ma, HK SAR, CN
- 20' Immunotherapy bi-specific approaches
Daniel S. W. Tan, SG
- 20' Antibody-drug conjugates: target vs payload
Dirk Laurent, DE
- 15' Q & A
- 12:05-13:05 **Lunch**
- 13:05-14:05 **Workshop 1: The Protocol/Study.**
Conducting the trial: Evaluating the Phase I package
Understanding the pre-clinical science, pre-clinical toxicity, pearls and pitfalls, starting dose, dose selection, pharmacology/pharmacodynamics
 - The decision-making process
 - Each session will review a Phase 1 Protocol and IB and highlight how to appraise them.
 Protocol review in 2 x 30' workshops-
Each reviews 1 protocol: An ADC and an immunotherapy (combo or bispecific)
- 14:05-15:20 **Session 4 – The Patient: Selection and Management**
Chairs: Jayesh Desai, AU and Brigitte Ma, HK SAR, CN
- 20' Patient selection: Genomic matching to phase I trials, NGS, ctDNA, existing programmes
Timothy A. Yap, US
- 20' Safety and adverse events management
Ben Tran, AU

- 20' Ethnic differences in drug tolerance and response or Pharmacodynamic variability and applications for drug development
Boon-Cher Goh, SG
- 15' Q and A and key patient factors to consider
- 15:20-16:35 **Session 5 - Meet your mentor: Building a career in Developmental Therapeutics**
Co-chairs: Jayesh Desai, AU and Elena Garralda, ES
- 20' Life in Academia
Brigette Ma, HK SAR, CN
- 20' Life in Industry
Ezogelin Gruyters, US (AstraZeneca)
- 20' The Clinical Trialist Perspective
Anastasios Stathis CH
- 15' Discussion and wrap-up of Day1

Friday, 18 July 2025

- 9:00-9:15 **Introduction to Day 2**
(Any of the co-Chairs)
- 9:15-10:30 **Session 6 - Understanding your Industry Partners and Trial Sponsor**
Co-chairs: Jayesh Desai, AU and Brigitte Ma, HK SAR, CN
- 15' The Principal Investigator's perspective, Becoming a good PI: Understanding Pharma and Biotech's expectations.
Jayesh Desai, AU
- 15' Industry's perspective: Challenges, how do we assess a site, metrics
Bruno Gomes, CH
- 15' Understanding and meeting expectations. Bridging the gap between the Site and the Sponsor
Elena Garralda, ES
- 30' Q and A

10:30-11:00 Coffee break

11:00-11:30 Lessons learned, questions

11:30-11:45 **Conclusions and Wrap-Up**

Jayesh Desai, AU, Elena Garralda, ES and Brigette Ma, HK SAR, CN