GOOD SCIENCE
BETTER MEDICINE
BEST PRACTICE

European Society for Medical Oncology

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 Lillian 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 Brigette 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.

GOOD SCIENCE
BETTER MEDICINE
BEST PRACTICE

European Society for Medical Oncology

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
Lillian 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 Brigette 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 Brigette 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 Brigette 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

GOOD SCIENCE
BETTER MEDICINE
BEST PRACTICE

European Society for Medical Oncology

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