ESMO ADVANCED COURSE PROGRAMME
EARLY DRUG DEVELOPMENT

24-25 February 2023
Singapore

CO-CHAIRS: Jayesh Desai, Australia
Elena Garralda, Spain
Brigette Ma, Hong Kong

SPEAKERS: Johanna Bendell, Switzerland
Josh C. C. Lin, Taiwan
Do-Youn Oh, Korea
Ruth Plummer, United Kingdom
Lin Shen, China
Toshio Shimizu, Japan
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 of 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, to regional and international engagement, and 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.

Friday, 24 February 2023

09:00-09:10  Welcome and course overview
             Jayesh Desai, AU, Elena Garralda, ES and Brigette Ma, HK

9:10-10:40   Session 1 - Phase I clinical trial design & methods
             Co-Chairs: Jayesh Desai, AU and Elena Garralda, ES
             25’ Importance of phase I trials in drug development: Historical perspective
             Lillian L. Siu, CA
             25’ Current designs of phase 1 clinical trials
             Ruth Plummer, UK
25’ Limitation of current designs and future designs
Josh C. C. Lin, TW

15’ Discussion & Survey
Faculty

10:40–11:10 Coffee break

11:10–12:40 Session 2 – Step-by-step development of specific classes of drugs, patient selection, relevant biomarkers and pharmacodynamics
Co-chairs: Elena Garralda, ES and Brigette Ma, HK

25’ Targeted therapy, biomarkers, combinatorial approach
Do-Youn Oh, KR

25’ Immunotherapy, biomarkers, combinational approach
Daniel S. W. Tan, SG

25’ Other agents: e.g. drug conjugates, hormonal agents, cell-based therapies, …
Anastasios Stathis, CH

15’ Discussion
Faculty

12:40–13:40 Lunch

13:40–15:30 Session 3 – Patient selection, response & toxicity assessment
Co-chairs: Jayesh Desai, AU and Brigette Ma, HK

25’ Patient selection: Genomic matching to phase I trials, NGS, ctDNA, existing programmes
Timothy A. Yap, US

25’ Safety and adverse events management
Ben Tran, AU

25’ Assessing response in phase I trials, neoadjuvant trials, RECIST, ir-RECIST, others, functional imaging
Toshio Shimizu, JP

25’ Ethnic differences in drug tolerance and response
Lin Shen, CN

10’ Discussion
Faculty

15:30–16:00 Coffee break
16:00-17:30   **Session 4 - Practical & Operational Aspects**  
Co-chairs: Elena Garralda, ES and Brigette Ma, HK

25’  Principal Investigator's perspective: Assessing protocol, logistics, budget, resource allocation, phase I centres or site-based trials units?  
Jayesh Desai, AU

25’  Industry’s perspective: Challenges, how to assess a site, metrics  
Johanna Bendell, CH

25’  Challenges: Facing Covid-19 and lessons learnt  
Jayesh Desai, AU, Elena Garralda, ES and Brigette Ma, HK

15’  Discussion  
Faculty

19:00  Networking dinner

---

**Saturday, 25 February 2023**

09:00-12:30   **Workshop sessions**  
Three parallel workshops sessions with around 20 delegates in each group  
(Delegates will attend all workshop sessions on a rotational basis)

- 10’ Introduction based on clinical cases presented by speakers  
- 45’ Discussion  
- 5’ Break

**Workshop 1**  
**Meet your mentor: Building a career in Developmental Therapeutics**  
Workshop leaders to discuss the following topics:
- Investigator-initiated trials and maximizing translational opportunities, Publishing papers in phase I, Developing a reputation as a phase I investigator, Working in and with Pharma/Biotech, Challenges in Covid-19 times, Special issues for Asian-Pacific region, Women/minorities related issues
- Mentoring junior faculties and building the workforce  
**Mentor:** Daniel S. W. Tan, SG  
**Mentor:** Johanna Bendell, CH

**Workshop 2**  
**Becoming a phase I manager: 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: Consider some case studies to highlight  
**Mentor:** Elena Garralda, ES  
**Mentor:** Ben Tran, AU
Workshop 3
60’
- Building a Phase I network in Asia-Pacific (AP) region
- Experience in AP region of consortium: Pros & Cons
- Special tumour sites in AP region: How to attract sponsorship
  Mentor: Brigette Ma, HK
  Mentor: Jayesh Desai, AU

11:00-11:30  Coffee break

11:30-12:30  Workshop continuation

12:30-13:00  Feedback on the workshops/Results of survey

13:00-13:10  Conclusions
  Jayesh Desai, AU, Elena Garralda, ES and Brigette Ma, HK

13:10-14:10  Lunch