ESMO ADVANCED COURSE PROGRAMME
EARLY DRUG DEVELOPMENT

2-4 February 2024
Hong Kong SAR, China

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

SPEAKERS
Johanna Bendell, Switzerland
Boon Cher Goh, Singapore
Ezogelin Gruyters, United States
Josh C.C. Lin, Taiwan
Do-Youn Oh, Republic of Korea
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.

ACCREDITATION

The programme of this event has been accredited with 15 ESMO-MORA category 1 points.
Recertification is necessary for medical oncologists to remain professionally certified by ESMO. Recertification guarantees that a certified medical oncologist has continued to update his/her knowledge and continues to possess the necessary skills and standards for the practice of medical oncology. For further details please refer to esmo.org.

ORGANISATION AND CONTACTS

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Friday, 2 February 2024

09:00-09:30  Welcome and course overview  
Jayesh Desai, AU, Elena Garralda, ES and Brigette Ma, HKSAR CN

9:30-11:00  Session 1 - Phase I clinical trial design & methods  
Co-Chairs: Jayesh Desai, AU and Elena Garralda, ES  
30’  The Importance of the phase I trial in the drug development process. Successes and lessons learned.  
Lillian L. Siu, CA  
30’  Current designs of phase 1 clinical trials and Limitations  
Ruth Plummer, UK  
30’  Q&A  
All

11:00-11:30  Coffee break

11:30-12:30  Session 2 – Round Table Introductions: Meet the Faculty and Attendees  
Aim to divide up faculty (12+3 co-chairs): 2-3 faculty/table. 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.

12:30-13:30  Lunch

13:30-15:30  Session 3 - Step by step development of specific classes of drugs, relevant biomarkers, pharmacodynamics  
Co-chairs: Elena Garralda, ES and Brigette Ma, HKSAR CN  
25’  Targeted therapies, biomarkers and combination approaches in the drug development setting: Dose optimization (OPTIMUS)  
Do-Youn Oh, KR  
25’  Immunotherapy: combination approaches and bi-specifics: Biomarkers, current approaches and what’s next?  
Daniel S. W. Tan, SG  
25’  Antibody-Drug Conjugates: Target vs payload, and understanding toxicity  
Josh C. C. Lin, TW
Emerging drug classes: Cellular therapies, novel vaccine approaches etc.
Anastasios Stathis, CH

Q&A
All

Coffee Break

Session 4: The Academia and Industry perspective: Strengths and challenges in bringing Phase I studies to region
Co-chairs: Facilitated by 1-2 co-Chairs, providing a regional perspective

The Academic perspective
Brigette Ma, HKSAR CN

The Industry perspective
Ezogelin Gruyters, US

Q&A
All

Saturday, 3 February 2024

Wrap-up of Day 1 and Introduction to Day 2
Elena Garralda, ES

Session 4 - Patient selection, response & toxicity assessment
Co-chairs: Jayesh Desai, AU and Brigette Ma, HK

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

Safety and adverse events management
Ben Tran, AU

Ethnic differences in drug tolerance and response
Boon-Cher Goh, SG

Q&A
All

Coffee break
11:15- 14:15  **Workshop sessions**
Three parallel workshops sessions with around 20 delegates in each group
(Delegates will attend all workshop sessions on a rotation basis)
  - 10' Introduction and examples: understanding the key elements
  - 45' Discussion
  - 5' Break

**Workshop 1**
60' **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, special issues for Asian-Pacific region. Diversity: Women/ minorities and related issues
  - Mentoring junior faculties and building the workforce
**Mentors:** Daniel S. W. Tan, SG, Lillian Siu, CA
**Mentors:** Johanna Bendell, CH

**Workshop 2**
60' **Building and running your Phase I Program – Key Operational Considerations**
Key operational issues to consider step by step: financial, budgets, internal and external regulatory factors. Building your team- clinical (medical/nursing) and non-clinical staff. Patient-centric considerations.
**Mentors:** Timothy A. Yap, US, Ruth Plummer, UK and Ezogelin Gruyters, US
**Mentors:** Josh C. C. Lin, TW and Brigette Ma, HKSAR CN

13:15-14:15  **Lunch**

14:15- 15:15  **Workshop sessions – Continuation**

**Workshop 3**
60' **Building a Phase I network in Asia-Pacific (AP) region**
Experience in AP region of consortia: Pros & Cons, What is needed?
**Mentors:**
Jayesh Desai, AU – Cancer Trials Australia (CTA)
Brigette Ma, HKSAR CN – NCI-CTEP, NRG oncology, Other cancer Consortium.
Mentors may invite participants to share their experience on stage.

15:15- 15:45  **Coffee Break**

15:45- 17:15  **Session 5 - Practical & Operational aspects**
**Co-chairs:** Elena Garralda, ES and Brigette Ma, HKSAR CN
  - 25’ The Principal Investigator’s perspective, Becoming a good PI: Understanding Pharma and Biotech's expectations.
    Jayesh Desai, AU
25’ Industry’s perspective: Challenges, how do we assess a site, metrics
Johanna Bendell, CH

25’ Understanding and meeting expectations. Bridging the gap between the Site and the Sponsor
Elena Garralda, ES

15’ Q&A
All

19:00 Networking dinner

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**Sunday, 4 February 2024**

9:00-9:15 Wrap-up of Day 1 and 2 and Introduction to Day 3
Jayesh Desay, AU

9:15-11:15 **Workshop sessions: Stepwise Approach, a Live Demonstration**

Workshop design: Two parallel workshop sessions with around 20/25 delegates in each group
(Delegates will attend both workshops sessions on a rotation basis)

10’ **Introduction:** Each workshop will focus on a different phase 1 protocol
and investigator brochure (IB) to be presented by mentors from the
other parallel workshop (e.g. different study designs, different class of
investigational drugs and combinations)

45’ **Discussion**

5’ **Break** to allow mentors to move over to next workshop room

**Workshop 4**

**Conducting the trial: Evaluating the Phase I package (Part A)**

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

**Mentors:** Elena Garralda, ES and Ben Tran, AU

**Mentors:** Johanna Bendell CH
Workshop 5 60'  Conducting the trial: Evaluating the Phase I package (Part B)
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
Mentors: Anastasios Stathis CH and Daniel S. W. Tan, SG
Mentors: Ezogelin Gruyters, US

11:15-11:45  Coffee break
11:45-12:15  Feedback on the workshops
12:15-12:30  Conclusions and Wrap-Up
Jayesh Desai, AU, Elena Garralda, ES and Brigette Ma, HKSAR CN

12:30-13:30  Lunch