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

ESMO Head Office
Education Department
Via Ginevra 4, 6900 Lugano, Switzerland
Email: **courses@esmo.org**
www.esmo.org

GOOD SCIENCE
BETTER MEDICINE
BEST PRACTICE

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

25’ Emerging drug classes: Cellular therapies, novel vaccine approaches etc.
Anastasios Stathis, CH

20’ Q&A
All

15:30-16:00 Coffee Break

16:00-17:00 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

25’ The Academic perspective
Brigette Ma, HKSAR CN

25’ The Industry perspective
Ezogelin Gruyters, US

10’ Q&A
All

Saturday, 3 February 2024

9:00-9:15 Wrap-up of Day 1 and Introduction to Day 2
Elena Garralda, ES

9:15-10:45 Session 4 - 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’ Ethnic differences in drug tolerance and response
Boon-Cher Goh, SG

15’ Q&A
All

10:45-11:15 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 Meet your mentor: Building a career in Developmental Therapeutics

60' 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 Building and running your Phase I Program – Key Operational Considerations

60' 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 Building a Phase I network in Asia-Pacific (AP) region

60' 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

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)

60’ 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 — Conducting the trial: Evaluating the Phase I package (Part B)

60’

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