ESMO Advanced Course on Early Drug Development

PROGRAMME

ESMO
ADVANCED COURSE

HONG KONG SAR CHINA
2-4 FEBRUARY 2024

Co-Chairs
Jayesh Desai, Australia
Elena Garralda, Spain
Brigette Ma, Hong Kong SAR, China

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EARLY DRUG DEVELOPMENT

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CO-CHAIRS

Jayesh Desai, Australia
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SPEAKERS

Boon-Cher Goh, Singapore
Bruno Gomes, Switzerland
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.

ACKNOWLEDGEMENTS

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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

09:30-11:00 Session 1 - Phase I clinical trial design and methods
Co-Chairs: Jayesh Desai, AU and Elena Garralda, ES

30' The importance of Phase I trial in the drug development process: Successes and lessons learnt
Lillian L. Siu, CA

30' Current designs of Phase I 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
Divide up faculty (11+3 co-chairs): 2-3 faculty/table.
Mutual introduction by Faculty and participants 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

09:00-09:15 Wrap-up of Day 1 and Introduction to Day 2
Elena Garralda, ES

09:15-10:45 Session 5 - Patient selection, response and toxicity assessment
Co-chairs: Jayesh Desai, AU and Brigette Ma, HKSAR CN

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' Pharmacodynamic variability and implications for drug development
Boon-Cher Goh, SG

15' Q&A
All

10:45-11:15 *Coffee break*

11:15- 15:15 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 (to allow mentors to move over to next workshop room)

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: Bruno Gomes, CH
Lillian L. Siu, CA
Daniel S. W. Tan, SG

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: Ezogelin Gruyters, US
Josh C. C. Lin, TW
Brigette Ma, HKSAR CN
Ruth Plummer, UK
Timothy A. Yap, US

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 may invite participants to share their experience on stage

Mentors: Jayesh Desai, AU (Cancer Trials Australia -CTA)
Brigette Ma, HKSAR CN (NCI-CTEP, NRG oncology, Other cancer Consortium)

15:15- 15:45 *Coffee Break*

15:45- 17:15 Session 6 - Practical and 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
Bruno Gomes, 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

09:00-09:15 Wrap-up of Day 1 and 2 and Introduction to Day 3
Jayesh Desay, AU

9:15-11:45 Workshop sessions: Stepwise Approach: A Live Demonstration
Workshop design: Two parallel workshop sessions with around 25/30 delegates in each group (Delegates will attend both workshops sessions on a rotation basis)
Each workshop will focus on a different Phase I 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)
10' Introduction:
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 I)
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 I Protocol and IB and highlight how to appraise them

Mentors: Elena Garralda, ES
Bruno Gomes, CH
Ben Tran, AU

Workshop 5 Conducting the trial: Evaluating the Phase I package (Part II)
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 I Protocol and IB and highlight how to appraise them

Mentors: Ezogelin Gruyters, US
Anastasios Stathis CH
Daniel S. W. Tan, SG

10:15-10:45 *Coffee break*

10:45-11:45 Workshop sessions – Continuation

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*

Notes

ORGANISATION AND CONTACTS

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