

## ESMO Advanced Course on Early Drug Development

### Programme

**ESMO  
ADVANCED COURSE**

**SINGAPORE  
24-25 FEBRUARY 2023**

**Chairs**

Jayesh Desai, Australia

Elena Garralda, Spain

Brigette Ma, Hong Kong

# ESMO ADVANCED COURSE PROGRAMME EARLY DRUG DEVELOPMENT

Singapore  
24-25 February 2023

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## CO-CHAIRS

Jayesh Desai, Australia  
Elena Garraida, Spain  
Brigette Ma, Hong Kong

## SPEAKERS

Johanna Bendell, Switzerland  
Boon-Cher Goh, Singapore  
Josh C. C. Lin, Taiwan  
Do-Youn Oh, Korea  
Ruth Plummer, United Kingdom  
Toshio Shimizu, Japan  
Lillian L. Siu, Canada  
Anastasios Stathis, Switzerland  
Daniel S. W. Tan, Singapore  
Ben Tran, Australia  
Timothy A. Yap, United States

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## 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

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## ACCREDITATION

The programme of this event has been accredited with **10 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](https://www.esmo.org).

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## ACKNOWLEDGEMENTS

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## ORGANISATION AND CONTACTS

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[www.esmo.org](https://www.esmo.org)



## Friday, 24 February 2023

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09:00-09:10	<b>Welcome and course overview</b> Jayesh Desai, AU, Elena Garralda, ES and Brigitte Ma, HK
09:10-10:40	<b>Session 1 - Phase I clinical trial design &amp; methods</b> <b>Co-Chairs: Jayesh Desai, AU and Elena Garralda, ES</b>
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	<b>Coffee break</b>
11:10-12:40	<b>Session 2 - Step-by-step development of specific classes of drugs, patient selection, relevant biomarkers and pharmacodynamics</b> <b>Co-chairs: Elena Garralda, ES and Brigitte Ma, HK</b>
25'	Targeted therapy, biomarkers, combinatorial approach Do-Youn Oh, KR
25'	Immunotherapy, biomarkers, combinatorial 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	<b>Lunch</b>
13:40-15:30	<b>Session 3 - Patient selection, response &amp; toxicity assessment</b> <b>Co-chairs: Jayesh Desai, AU and Brigitte Ma, HK</b>
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 efficacy in novel phase I trials Toshio Shimizu, JP
25'	Ethnic differences in drug tolerance and response Boon-Cher Goh, SG
10'	Discussion Faculty
15:30-16:00	<b>Coffee break</b>

16:00-17:30	<b>Session 4 - Practical &amp; Operational Aspects</b> <b>Co-chairs: Elena Garralda, ES and Brigitte Ma, HK</b>
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 Brigitte Ma, HK
15'	Discussion Faculty
18:00	<b>Networking dinner</b>

## Saturday, 25 February 2023

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09:00-12:30	<b>Workshop sessions</b> 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
<b>Workshop 1</b> 60'	<b>Meet your mentor: Building a career in Developmental Therapeutics</b> Workshop leaders to discuss the following topics: <ul style="list-style-type: none"> <li>- 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</li> <li>- Mentoring junior faculties and building the workforce</li> </ul> <b>Mentor:</b> Daniel S. W. Tan, SG <b>Mentor:</b> Johanna Bendell, CH
<b>Workshop 2</b> 60'	<b>Becoming a phase I manager: Evaluating the Phase I package</b> <ul style="list-style-type: none"> <li>- Understanding the pre-clinical science, pre-clinical toxicity, pearls and pitfalls, starting dose, dose selection, pharmacology/pharmacodynamics</li> <li>- The decision-making process: Consider some case studies to highlight</li> </ul> <b>Mentor:</b> Elena Garralda, ES <b>Mentor:</b> Ben Tran, AU
<b>Workshop 3</b> 60'	<b>Building a Phase I network in the Asia-Pacific (AP) region</b> <ul style="list-style-type: none"> <li>- Experience in AP region of consortium: Pros &amp; Cons</li> <li>- Special tumour sites in AP region: How to attract sponsorship</li> </ul> <b>Mentor:</b> Brigitte Ma, HK <b>Mentor:</b> Jayesh Desai, AU
11:00-11:30	<b>Coffee break</b>
11:30-12:30	<b>Workshop continuation</b>
12:30-13:00	<b>Feedback on the workshops/Results of survey</b>
13:00-13:10	<b>Conclusions</b> Jayesh Desai, AU, Elena Garralda, ES and Brigitte Ma, HK
13:10-14:10	<b>Lunch</b>