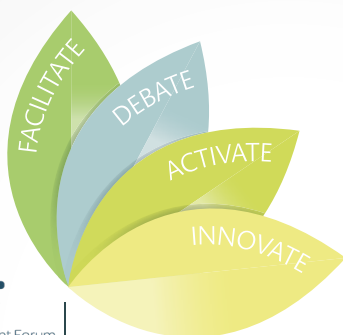




CDDF

Cancer Drug Development Forum



SPRING
CONFERENCE
2020

THE NETHERLANDS
10-12 FEBRUARY 2020

CDDF SPRING CONFERENCE 2020

NOORDWIJK AAN ZEE, NETHERLANDS

PROGRAMME

→ WWW.CDDF.ORG



WELCOME NOTE

Dear participants,

On behalf of the Cancer Drug Development Forum, its partners, and my colleagues from the organizing committee, Stefan Schwoch, Irmela Radtke, and Paul Stockman, I would like to welcome you to the 2020 CDDF Spring Meeting, at the Radisson Blu Hotel in Noordwijk aan Zee, Netherlands.

Successor of the former CDDF Alpine Conference, this Spring Conference is the 11th meeting of its kind, where we gather the leaders in the world of innovative cancer therapy development and create a platform with lectures, case studies, and moderated discussions on innovative drug development. Now for the first time held in the Netherlands.

The program of this multi-stakeholder meeting will feature: the relevance of individual components in combination therapies, tumor agnostic drug development, cell therapies, reflections and discussions on Regulatory Strategic Science.

We are excited with the marvelous speakers who have accepted our invitation and thrilled by the major contributions of representatives from both, EMA and FDA.

Many clinical researchers, pharmaceutical industry representatives, and patient advocacy representatives, will join us in undoubtedly lively discussions. We have left ample time for these exchanges.

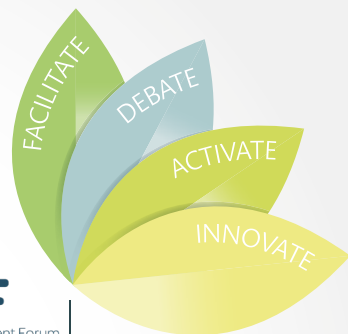
We would like to remind you to join us at the two networking dinners. They have been set in a way that will allow optimal time for further discussions.

I take great pleasure in welcoming you to our biggest event of the year.

We are looking forward to sharing these discussions with you, they are at the core of our mission to facilitate oncology drug development.

Jaap Verweij,

Managing Director CDDF
Programme Chair



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EVENT OUTLINE

The Cancer Drug Development Forum (CDDF) Spring conference 2020 is a unique forum that convenes every 18 months and gathers the leaders in the world of innovative cancer therapy development, including medical researchers, pharmaceutical industry representatives, regulatory authority representatives and patient advocacy groups. It is the successor of the former CDDF Alpine Conference and the 11th edition takes place from 10 to 12 February 2020, in Noordwijk aan Zee, the Netherlands.

This multi-stakeholder, interactive meeting offers plenary lectures with moderated discussions, including case studies and networking opportunities. The programme focuses on the latest and future challenges with a special emphasis on rational combination therapies, tumor agnostic drug development, cellular therapies, and regulatory guidance on oncology drug development.

PROGRAMME COMMITTEE

- Jaap Verweij (CDDF Board, NL) - Programme Chair
- Stefan Schwoch (Lilly, UK)
- Irmela Radtke (Roche, CH)
- Paul Stockman (Astrazeneca, UK)

MEETING VENUE

Radisson Blu Hotel, Noordwijk aan Zee in NL

Picplein 8, 2202 CL Noordwijk aan Zee, Netherlands
+31 71 365 3000

MEETING ROOM

Jan de Raad 1-2-3 on the ground floor

MEETING SECRETARIAT

Cancer Drug Development Forum (CDDF) - info@cddf.org - www.cddf.org
c/o BLSI Clos Chapelle-aux-Champs 30, 1200 Brussels, Belgium

PROGRAMME

DAY 1 – MONDAY 10 FEBRUARY 2020

12:00	 Lunch (60')
	Welcome Note Jaap Verweij (CDDF Board, NL)
TOPIC 1: THE RELEVANCE OF INDIVIDUAL COMPONENTS IN COMBINATION THERAPIES	
Session Chairs: Irmela Radtke (Roche, CH) & Martina Schüssler-Lenz (CAT Chair, Committee for Advanced Therapies, EMA, NL)	
13:00	Pharmacological & Clinical Trial Design Aspects Ruth Plummer (Newcastle University, UK)
13:30	Pharma-Industry Perspective Stefan Schwoch (Lilly, UK)
14:00	Regulatory Aspects and Guidances Jorge Camarero (Spanish Agency of Medicines and Medical Devices, ES)
	Novel Preclinical Models to Assess the Value of New Drug Combinations James Doroshow (National Cancer Institute, US) <i>Dr. Doroshow will give a presentation on novel preclinical models on the second day. Please refer to the Day 2 programme.</i>
14:30	 Discussion (45')
15:15	 Coffee Break (30') - Foyer
TOPIC 2: REFLECTION ON CDDF WORKSHOPS OF LAST 18 MONTHS	
Session Chair: Jaap Verweij (CDDF)	
15:45	Biomarkers and Patient's Access to Personalized Oncology Drugs in Europe Annie Pannelay (Romanian Health Observatory, UK)
16:00	 Discussion (15')
16:15	Minimal Residual Disease (AML/CLL) Irmela Radtke (Roche, CH)
16:30	 Discussion (15')
16:45	Involving Patients in Oncology Drug Development Claudia Hey (Merck Healthcare KGaA, DE)
17:00	 Discussion (15')
17:15	The Use of Real-World Data to Optimize Oncology Drug Development and Access Axel Glasmacher (CDDF, DE)
17:30	 Discussion (15')
18:45	Bus departure to Beach Club O
19:00	 Welcome Drink (Beach Club O) - Presentation on recent updates within CDDF
19:30	 Networking Dinner (Beach Club O) - Presentation on AAADV
A shuttle bus to the hotel runs every 15 minutes from 21:00 to 22:30	

DAY 2 – TUESDAY 11 FEBRUARY 2020

TOPIC 3: TUMOR AGNOSTIC DRUG DEVELOPMENT

Session Chairs: Stefan Schwoch (Lilly, UK) & Herbert Kim Lyerly (Accelerating Anticancer Agent Development and Validation, US)

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| 09:00 | Medical Aspects
Irene Braña (Vall d'Hebron Institute of Oncology, ES) |
| 09:35 | Pharmaceutical Industry Aspects
Todd Riehl (Genentech, US) |
| 10:10 | Case-Study: Tumor Agnostic Approval of Larotrectinib
Chitkala Kalidas (Bayer, US) |
| 10:40 | ☕ Coffee Break (20') - Foyer |
| 11:00 | Regulatory Aspects
Elias Pean (EMA, NL) |
| 11:35 | 🗣️ Discussion (20') |
| 12:05 | Bus departure to Alexander Beach Club |
| 12:15 | 🍽️ Lunch (60') - Alexander Beach Club |
| 13:20 | Bus departure to the hotel |
| 13:40 | Return to the meeting room |
| 13:45 | [Topic 1]: THE RELEVANCE OF INDIVIDUAL COMPONENTS IN COMBINATION THERAPIES
Novel Preclinical Models to Assess the Value of New Drug Combinations
James Doroshow (National Cancer Institute, US) |

TOPIC 4: CELLULAR THERAPIES (INCL. CAR-T CELL THERAPIES)

Session Chairs: Axel Glasmacher (CDDF, DE) & Giovanni Tafuri (EUnetHTA, NL)

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| 14:15 | Progress in Haematological Malignancies
Gerhard Ehninger (Cellex, DE) |
| 15:00 | Status in Solid Tumors
Victor Moreno Garcia (START Madrid FJD, ES) |
| 15:45 | ☕ Coffee Break (30') - Foyer |
| 16:15 | Regulatory Aspects
Martina Schüssler-Lenz (CAT Chair, Committee for Advanced Therapies, EMA, NL) |
| 17:00 | HTA Issues
Stephen Palmer (York University, UK) |
| 17:45 | 🗣️ Discussion (30') |
| 19:00 | 🍷 Networking Dinner (Jan de Raad 6-7) |

DAY 3 – WEDNESDAY 12 FEBRUARY 2020

TOPIC 5: REGULATORY GUIDANCE ON ONCOLOGY DRUG DEVELOPMENT	
Session Chairs: Paul Stockman (Astrazeneca, UK) & Ralf Herold (European Medicines Agency, NL)	
09:00	Update on the Revision of EMA Anti-Cancer Guideline & Regulatory Science Strategy 2025 Sigrid Klaar (Swedish Medical Products Agency, SE) & Ralf Herold (EMA, NL)
09:45	FDA Guidelines Richard Pazdur (FDA, US)
10:30	 Coffee Break (30') - Foyer
11:00	Industry Aspect Eric Rubin (Merck, US)
11:45	 Panel discussion (45') Moderator: John Smyth (CDDF, UK)
12:30	Wrap-Up and Closure & Lunch (Foyer)
13:15	Bus Departure to the Schiphol Airport <i>A coach bus for meeting participants departs for the Schiphol airport at 13.15.</i>