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Cancer Drug Development Forum
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CDDF
MULTI-STAKEHOLDER
WORKSHOP

3-4 APRIL 2023

Dose optimization in early oncology drug development

HYBRID WORKSHOP

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EVENT OUTLINE

In early cancer drug development, we are amid of an important transition: From the pursuit of the maximum tolerated dose (MTD) that dominated the development of cytotoxic chemotherapy to the attempt to define the biological optimal dose for targeted anti-cancer agents and immune oncology treatments .

This transition – accentuated by the FDA's Project Optimus and the agency's draft guidance on dose-optimization – will require significant changes to the early development of anti-cancer agents. With additional dose-optimization studies development timelines and costs will increase but it is also clear that non-optimized dosing is likely to reduce the efficacy and increase the toxicity of an agent.

New study designs, pre-clinical research, updated mathematical modelling of PK/PD relationships and potentially new early endpoints (e.g. ctDNA) are among the sophisticated tools needed to achieve a new balance in early drug development.

A very interesting aspect is the exploration of the use of patient-reported outcomes early in drug development for dose-optimization based on short- and longer tolerability. These data could provide important additional information for dose selection and could lead to an earlier understanding of the patient experience.

The workshop will offer a neutral and collaborative platform for evaluation and discussion of innovation in these areas with active participants from all relevant stakeholders. Informative lectures and panel discussions open to all attendees will alternate.

The main objective of the workshop will be to formulate how dose optimization in the future could be implemented in early drug development based on new methodologies, but also considering the views from all relevant stakeholders. CDDF intends to publish the outcome .

LEARNING OBJECTIVES

- Explore challenges to the implementation of dose-finding studies in oncology
- Discuss opportunities to improve dosing strategies given ongoing challenges
- Identify key considerations for selecting appropriate dose optimization strategies in oncology in light of FDA's project OPTIMUS
- Potential implications of project OPTIMUS for dose-finding strategies in oncology early development in Europe and beyond

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PROGRAMME COMMITTEE

- Axel Glasmacher (CDDF, DE)
- Katrin Rupalla (CDDF, CH)
- Harald Weber (Seagen, CH)
- Chunze Li (Roche, US)

TARGET AUDIENCE

The target is a multidisciplinary audience of academia representatives, EU and US regulatory bodies (EMA, FDA, National Agencies), pharmaceutical industry, HTAs and patient advocates.

MEETING VENUE & EVENT PLATFORM

Movenpick hotel Amsterdam City Centre

Piet Heinkade 11

Amsterdam, The Netherlands

The workshop will take place in Amsterdam and online via Brella platform. Only approved participants will receive an information including the link to the platform and log-in details closer to the date.

CONTACT

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PROGRAMME

Day 1 – Monday 3 April 2023

12:00 - 12:45	Lunch
12:50 - 13:00	Welcome note Axel Glasmacher (CDDF, DE)
13:00 - 13:20	Keynote lecture: The need for dose optimization in early drug development Mark J. Ratain (Uchicago Medicine, USA)
SESSION 1: THE CHALLENGES OF DOSE OPTIMIZATION	
Session chairs: Katrin Rupalla (CDDF, CH) & Axel Glasmacher (CDDF, DE)	
13:20 - 13:35	Clinician perspective Elena Garralda (VHIO, ES)
13:35 - 13:50	Regulator's perspective Filip Josephson (Lakemedelsverket, SE)
13:50 - 14:05	Patient perspective Hans Scheurer (WECAN, NL)
14:05 - 14:20	Industry perspective Harald Weber (Seagen, CH)
14:20 - 15:20	Panel discussion Moderators: session chairs, Panelists: speakers & Dr Benoy Daniel (MHRA, UK)
15:20 - 15:50	Coffee break

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SESSION 2: PROJECT OPTIMUS AND OTHER REGULATORY INITIATIVES	
Session chairs: Hemal Morjaria (J&J, UK), Filip Josephson (Lakemedelsverket, SE)	
15:50 - 16:05	Goals and status of Project Optimus Stacy Shord, PharmD (FDA, US)
16:05 - 16:20	Patient contribution to Project Optimus Dr. Hillary Stires (FOCR, US)
16:20 - 16:50	Panel discussion Moderators: session chairs, Panelists: speakers & Dr Benoy Daniel (MHRA, UK)
SESSION 3: DOSE OPTIMIZATION - METHODOLOGICAL APPROACHES	
Session chairs: Stefan Symeonides (CDDF, UK) & Blanca Garcia-Ochoa Martín (AEMPS, ES)	
16:50 - 17:05	Using tumor evolutionary theory to inform optimal doses Carter (Yanguang) Cao (Uiversity of North Carolina, US)
17:05 - 17:20	Biomarker consideration & translational modelling Weirong Wang (Johnson & Johnson, US)
17:20 - 17:35	New statistical concepts for Phase 1 and Phase 2 studies Ulrich Beyer (Roche, CH)
17:35 - 18:00	Panel discussion Moderators: session chairs, Panelists: speakers
19:30 - 21:00	Welcome drink & Networking dinner

PROGRAMME

Day 2 – Tuesday 4 April 2023

SESSION 4: DOSE OPTIMIZATION - OPTIONS FOR THE PATH FORWARD	
Session chairs: Chunze Li (Roche, US) & Harald Weber (Seagen, CH)	
10:30 - 10:45	Optimised dosing - how to optimize the trade-offs? Chunze Li (Roche, US)
10:45 - 11:00	Safety and toxicity Sophie Postel-Vinay (Gustave Roussy, FR)
11:00 - 11:15	Integrating patient-reported outcomes Chad Gwaltney (Gwaltney Consulting, US)
11:15 - 11:45	Coffee break
11:45- 12:00	Academic percpective (with case studies) Johann de Bono (ICR, UK)
12:00 - 12:15	Industry perspective (IQ, industry consortium, with case studies) Divya Samineni (Roche, US)

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SESSION 5: WRAPPING UP	
Session chairs: Axel Glasmacher (CDDF, DE) & Katrin Rupalla (CDDF, CH)	
12:15 - 13:30	Discussions and formulating recommendations coming out of the workshop Moderators: Axel Glasmacher (CDDF, DE) & Katrin Rupalla (CDDF, CH) Panelists: Chunze Li (Roche, US) & Harald Weber (Seagen, CH) , Johann de Bono (consultant in ICR, UK), Ulrich Beyer (Roche, CH) & Harald Enzmann (Bfarm, DE)
13:30 - 13:35	Close of the meeting & farewell Katrin Rupalla (CDDF, CH)
13:35 - 14:00	Sandwich lunch & departure