



CDDF
MULTI-STAKEHOLDER
WORKSHOP

14-15 NOVEMBER 2022

Histology independent drug development – is this
the future for cancer drugs?

HYBRID WORKSHOP



EVENT OUTLINE

Interactive workshop with participants from academia, industry, and the regulators exploring the opportunities and challenges in tumour agnostic cancer drug development.

Sessions will discuss the successes and failures of previous trials in this area, explore trial design, and discuss biomarker development for patient stratification.

LEARNING OBJECTIVES

- To understand the current landscape of tumour agnostic drug development
- To be able to discuss suitable trial designs to deliver such studies
- To develop an understanding of biomarker development and need for agnostic tumour registrations
- To understand the regulatory environment around these registrations



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PROGRAMME COMMITTEE

- Ruth Plummer (CDDF, UK)
- Chitkala Kalidas (Bayer, US)
- Brian Simmons (Roche, US)
- Sacha Wissink (MSD, NL)
- Bettina Ryll (MPNE, SE)

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

Meeting room: Matterhorn 1-2

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

Cancer Drug Development Forum (CDDF)

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PROGRAMME

Day 1 – Monday 14 november 2022

12:00 - 12:45	Lunch Atrium foyer
12:50 - 13:00	Welcome note Ruth Plummer (CDDF, UK)
SESSION 1: LESSONS LEARNED FROM PREVIOUS TRIALS - SUCCESSES AND FAILURES	
Session chairs: Ruth Plummer (CDDF, UK) & Jaap Verweij (CDDF, NL)	
13:00 - 13:15	Introduction / overview of successes Alastair Greystoke (Newcastle University, UK)
13:15 - 13:30	Regulatory perspective Elias Pean (EMA, NL)
13:30 - 13:45	Moving from experimental phase to evidence-based practice, a payer's perspective Sahar Barjesteh van Waalwijk van Doorn-Khosrovani (CZ, NL)
13:45 - 14:35	Panel discussion Moderators: session chairs, Panelists: speakers + Dr Steven Lemery (FDA, US)
14:35 - 15:00	Coffee break Atrium foyer
SESSION 2: BIOMARKER DEVELOPMENT AND OPTIMISATION	
Session chairs: Brian Simmons (Roche, US) & Sacha Wissink (MSD, NL)	
15:00 - 15:15	Scene-setting (in a forward looking way) Sid Mathur (MSD, US)
15:15 - 15:30	Industry perspective Lynn Brown (MSD, US)

15:30 - 15:45	Regulatory perspective Hilke Zander (Paul-Elrich Institut, DE)
15:45 - 15:55	Break
15:55 - 16:10	Evolution of comprehensive genomic profiling in precision medicine David Fabrizio (Foundation Medicine, US)
16:10 - 16:25	Biomarker harmonisation: TMB case study Jeff Allen (Friends of Cancer Research, US)
16:25 - 17:25	Panel discussion Moderators: session chairs, Panelists: speakers
19:30 - 22:00	Welcome drink & networking dinner Restaurant: Silk road 3

PROGRAMME

Day 2 – TUESDAY 15 november 2022

SESSION 3: TRIALS DESIGN - BASKET OR UMBRELLA FOR OPTIMAL PROGRESS

Session chairs: Chitkala Kalidas (Bayer, US) & Alastair Greystoke (Newcastle University, UK)

10:00 - 10:05	Introduction Session chairs
10:05 - 10:20	Regulatory perspective Dr Theodor Framke (EMA, NL)
10:20 - 10:35	Academic perspective Prof Lucinda Billingham (University of Birmingham, UK)
10:35 - 10:50	Early phase side of drug development - Industry perspective Richardus Vonk (Bayer, DE)
10:50 - 11:40	Panel discussion Moderators: session chairs, Panelists: speakers + Dr Steven Lemery (FDA, US)
11:40 - 12:00	Coffee break Atrium foyer

SESSION 4: LEVERAGING THE POTENTIAL OF PRECISION MEDICINE: ENSURING EQUITY OF ACCESS TO PRECISION DIAGNOSTICS AND TREATMENTS FOR PATIENTS

Session chairs: Bettina Ryll (MPNE, SE) & Olga Valcina (Onco Alliance, LV)

12:00 - 12:05	Introduction Bettina Ryll (MPNE, SE)
12:05 - 12:20	Why equality and quality matters Olga Valcina (OncoAlliance, LV, Deputy Director on Laboratory Matters, Institute of Food Safety, Animal Health and Environment "BIOR")

12:20 - 12:35	Genomic standards Prof Eivind Hovig (University of Oslo, NO)
12:35 - 12:50	Distributed data governance - Addressing the precision public health dilemma Philippe Page (The Human Colossus, CH)
12:50 - 13:15	Panel discussion Moderators: session chairs, Panelists: speakers
13:15 - 13:20	Farewell Jaap Verweij (CDDF, NL)
13:20 - 14:20	Take-away lunch Atrium foyer