



CDDF
MULTI-STAKEHOLDER
WORKSHOP

29-30 NOVEMBER 2021

Gene-and Cell Therapies in Oncology

HYBRID WORKSHOP

EVENT OUTLINE

PROGRAMME COMMITTEE

- Catarina Edfjäll (CDDF Board, CH)
- Ash Das-Gupta (GSK, CH)
- Simona Paratore (Bovartis, IT)
- Martina Schuesler-Lenz (PEI, EMA Committee for Advanced Therapies chair, DE)
- Hans Scheurer (MPE, BE)
- Natacha Bolaños (Lymphoma Coalition, ES)

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.

EVENT PLATFORM

The workshop will be held online via the unique event platform (as the CDDF Multi-Stakeholder Workshop on Endpoint In Cancer Drug Development). 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 29 NOVEMBER 2021

14:00 - 14:05	Welcome note Catarina Edfjäll (CDDF, SE)
SESSION 1: WHO IS THE GENE AND CELL CANCER-KILLER: DEEP DIVE ON THE GENE AND CELL SCIENTIFIC APPROACHES IN ONCOLOGY	
Session Chairs: Simona Paratore (Novartis, IT); Alessandro Aiuti (San Raffaele Hospital, IT)	
14:05 - 14:20	Cancer killer profile: T cell fitness, autologous or allo T cell, Tcell or NK? TBC
14:20 - 14:35	How to generate a cancer killer: is the use of a virus the way? CART or TCR? Emma Morris (University College London, UK)
14:35 - 14:50	Tumour and immunological environment influences in haematologic and solid tumours: engineering techniques or drug combination? TBC
14:50 - 15:30	Panel Discussion
15:30 - 16:00	Coffee Break
SESSION 2: HOW TO DEVELOP A GENE AND CELL CANCER KILLER: THE CLINICAL TRIALS.	
Challenges in timely initiation and conduct of clinical trials in gene and cell therapies in hematology. From planning to trial authorisation to patient treatment and follow up	
Session Chairs: Martina Schuessler-Lenz (Paul-Ehrlich-Institut; EMA CAT chair, DE) & Ulrich Jaeger (Medical University of Vienna, AT)	
16:00 - 16:10	Session opening

16:10 - 16:25	From clinical trials to marketing authorisation of advanced therapies Martina Schuessler-Lenz, (PEI; EMA Committee for Advanced Therapies chair, DE)
16:25-16:40	Approval pathways for innovative gene & cell therapies Adnan Jaigirdar (FDA, USA)
16:40 - 16:55	Clinical trials with gene and cell therapies – challenges and opportunities. The industry perspective Laura Pierce (GSK, USA)
16:55 - 17:10	Challenges and learnings in conducting clinical trials with gene and cell therapies – the investigator perspective TBC
17:10 - 17:50	Panel Discussion
18:00 - 19:00	CDDF Board and Industry Panel meeting
19:00 - 22:00	Networking dinner

DAY 2 – TUESDAY 30 NOVEMBER 2021

SESSION 3: HOW TO BRING A GENE AND CELL CANCER KILLER TO PATIENTS: HOW TO IMPROVE PATIENT ACCESS

Session Chairs: Catarina Edfjäll (CDDF, SE); Hans Scheurer (MPE, NL)

10:30 - 10:40	Session opening
10:40 - 10:55	From marketing authorisation to patient access - the rollout from the industry perspective Bernd Eschgfaeller (Novartis, CH)

10:55 - 11:10	Patient perspective Kate Morgan (MPE, UK)
11:10 - 11:25	HTA perspective and reimbursement models TBC
11:25 - 12:00	Panel Discussion
12:00 - 13:00	Lunch Break
SESSION 4: FUTURE PERSPECTIVE IN THE ECO-SYSTEM	
Session Chairs: Darko Miljkovic (GSK, CH); Axel Glasmacher (CDDF, DE)	
13:00 - 13:10	Session opening
13:10 - 13:25	EBMT perspective Nicolaus Kroeger (Medical Center Hamburg-Eppendorf, DE)
13:25 - 13:40	Synthetic Control Arm Amili Bratton (IQVIA, US)
13:40 - 13:55	Artificial Intelligence Thomas Clozel (Okwin, FR)
13:55 - 14:10	TBC TBC
14:10 - 14:50	Panel Discussion
14:50 - 15:00	Farewell